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# POTENTIAL HEALTH EFFECTS IN HUMAN POPULATIONS FROM EXPOSURE TO ETHYLENE DIBROMIDE

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## HEARING

BEFORE THE

## COMMITTEE ON AGRICULTURE, NUTRITION, AND FORESTRY
## UNITED STATES SENATE

NINETY-EIGHTH CONGRESS

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# POTENTIAL HEALTH EFFECTS IN HUMAN POPULATIONS FROM EXPOSURE TO ETHYLENE DIBROMIDE

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MONDAY, JANUARY 23, 1984

U.S. SENATE,
COMMITTEE ON AGRICULTURE, NUTRITION, AND FORESTRY,
*Orlando, Fla.*

The committee met, pursuant to notice, at 8:30 a.m., in the city hall, Hon. Paula Hawkins presiding.

Present: Senator Hawkins.

## STATEMENT OF HON. PAULA HAWKINS, A U.S. SENATOR FROM FLORIDA

Senator HAWKINS. Good morning. I am Senator Paula Hawkins. This U.S. Senate Agriculture Committee hearing has been called to determine whether our food, our water, and our air contain dangerous levels of the toxic chemical ethylene dibromide, commonly referred to as EDB. Every American has the right to know if the food he eats, the water he drinks, and the air he breathes is safe.

Serious questions have been raised about EDB because EDB has been found in food and drinking water at levels believed unsafe if consumed over long periods. Reports that our Nation's grain supply may be endangered needs to be carefully investigated. Removing various products from the shelf has left consumers bewildered and confused. All of this has led to an unacceptable level of chaos in the marketplace. Confusion in Florida is especially great because citizens in neighboring communities have been warned not to drink water from their own wells.

These are serious issues. Therefore, the committee has asked those with relevant information to appear here in Orlando today. It is my hope the public can learn from an open forum, such as this, the truth about EDB. This testimony will also become part of the public record used by the Congress to determine what administrative and legislative steps are required to better protect public health. I anticipate that other congressional committees will also investigate EDB use in the coming weeks.

The Environmental Protection Agency has found that the long-term danger posed by EDB use is real. For that reason, in September, it ordered an immediate halt to the major agricultural use of EDB as a way to kill underground insects that damage various agriculture commodities. It also ordered manufacturers not to use EDB on stored grain or in mills beginning this September. The agency also asked growers and tropical fruit importers to find a way to control fruit flies without using EDB.

Some health officials feel that EPA has not done enough and have taken independent emergency steps in the name of public health. Others believe that EPA has already gone too far, that EDB is overrated as a threat to humans, and calls for emergency action are irresponsible. I hope this hearing can narrow the range of opinion on what should be done.

To help sort out these essential issues, three panels will testify today. The first panel is composed of Federal officials responsible for regulating the nationwide use of EDB. The second panel will present industry's view of the EDB debate. The third panel will be composed of Florida officials who have been at the forefront of the EDB controversy.

I would like the first panel to step forward.

Our first witness is Edwin L. Johnson, Director, Office of Pesticides, at the U.S. Environmental Protection Agency. We thank you for coming here today.

The second witness will be John R. Wessel, who is the scientific coordinator, Office of the Associate Commissioner of Regulatory Affairs at the Food and Drug Administration. And our third witness will be Karen Darling, Deputy Assistant Secretary for Marketing and Inspection Services for the U.S. Department of Agriculture.

## STATEMENT OF EDWIN L. JOHNSON, DIRECTOR, OFFICE OF PESTICIDE PROGRAMS, U.S. ENVIRONMENTAL PROTECTION AGENCY

Mr. Johnson. Good morning. With your permission, I would like to summarize my prepared statement and ask you if I may insert the entire statement into the record?[1]

Senator Hawkins. No objection.

Mr. Johnson. Thank you. I'm glad to be here this morning to discuss with the committee EPA's position and actions concerning the pesticide ethylene dibromide.

The principal concerns arise from reported findings of EDB residues in a variety of grain-based food products, water, and citrus fruit fumigated for quarantine purposes. Federal and State agencies, as well as members of the public, are concerned about the health significance of EDB residues in these foods. An additional cause for concern has arisen in several States, including Florida, where EDB residues have been found in well water. I do not come here today with answers to all the questions about EDB. However, I want to assure the committee that EPA recognizes its responsibility to take action at the Federal level to deal with EDB residues in a way that will protect public health. The agency is working hard to meet that responsibility, but we also need to insure that our actions are based on a responsible evaluation of EDB, based on the best information available.

It is EPA's position, as noted in your opening remarks, that the risks and benefits of this chemical were clearly set out in a regulatory decision of September 28, 1983. EDB has been used for over 35 years and has been valuable in destroying insects in soil, grain, and citrus.

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[1] See p. 57 for the prepared statement of Mr. Johnson.

The balance between the risks and benefits have changed in recent years due to increased concerns about potential health effects and the development of alternatives for most major uses. Based on a detailed evaluation of health effects and economic benefits data, we concluded that for all the major uses of EDB as a pesticide, the risks of continued use outweigh the benefits and registration should be canceled. However, our decisions did include distinctions between the major uses of EDB which need to be understood.

For the soil fumigation use, which accounted for over 90 percent of the use of the EDB as a pesticide, we took the strongest action possible under the Federal Insecticide, Fungicide, and Rodenticide Act, an emergency suspension which immediately halted the sale and distribution of EDB products. This use was already causing ground water contamination in several States. For post-harvest fumigation of citrus and tropical fruits, we issued a notice of intent to cancel to become effective September 1, 1984. This relatively short phaseout period was intended to allow for commercial introduction of alternatives to EDB fumigation of domestic and foreign quarantine requirements. For fumigation of stored grain and the spot fumigation of grain-milling machinery, we also issued a notice of intent to cancel the use of EDB effective in 30 days. However, registrants of these uses and other interested parties appealed the cancellation notices, and as the FIFRA provides, nonsuspended uses may continue during cancellation proceedings, which may last up to 2 years, based on past experience.

But as we said in our September notices, EPA's concern about EDB is not whether major pesticide uses should be allowed to continue. We feel that these uses should all stop and EDB should be removed from the market. The issue before us now is whether public health will be endangered by the use of EDB while cancellation hearings take place. To decide this issue, we first need a good estimate of the extent to which EDB residues actually occur in the food supply. EPA has taken several steps to obtain this critical information.

We are gathering the necessary facts now and are considering three actions. The first issue to be decided is whether to issue emergency suspension notices in addition to the cancellation notices already in place, to stop immediately the nonsuspended uses. Specifically, we're considering the possibility of emergency suspension for the grain fumigants and fumigation uses for citrus and tropical fruits. Second, we are looking at what levels of residue are acceptable in the food supply in making recommendations in that area. And, third, we are moving to remove impediments to Federal enforcement actions, which now exist in our regulations. I would like to emphasize that our concern about EDB is for chronic effects due to long-term exposure to consumers, not for the risk of an acutely toxic effect.

Let me summarize information on EDB residues in grain-based foods. The U.S. Department of Agriculture, the Food and Drug Administration and various States have been very active in monitoring at all levels of the food supply. They have provided us with a great deal of information. For raw grain, we have found some high levels, but the real question is to the extent to which the U.S. grain supply is fumigated with EDB which estimates range from 5 percent up to 40 percent. With respect to milled products, such as flour, we are finding that there are a great number of positive findings of EDB.

However, they are in the low-to-middle part per billion range. About a third of the cake mixes and other preparations that the consumers bring home to cook themselves have been found to contain varying levels of EDB generally in the range of 1 part per billion to 100 parts per billion. Ready-to-consume products, that is those that consumers buy off of the shelf and consume with no further processing, generally don't show residues of EDB, and this includes such items as breads, baby foods, prepared cakes, and things of this sort.

It's important to look at these figures in terms of the processing that takes place after the material is purchased by the consumer, such as for flour, cake mixes, hush puppy mixes, and similar items. We have found that cooking reduces the residues in these materials quite significantly, on the order of 90 percent on the average.

We also have data on the meat supply that was obtained by the U.S. Department of Agriculture, and we found only 1 positive sample in 330 samples of meat and poultry taken by them, so we feel the meat supply, even though cattle and poultry are fed grain which could contain EDB, does not pose a threat to the diet of American consumers. We are continuing these efforts to gather more data.

Administrator Ruckelshaus sent a letter to the States asking them to provide information that they may have available to them by the end of this month. Similarly, our deputy administrator, Al Alm, wrote to the U.S. Department of Agriculture and the Food and Drug Administration asking for further accelerated cooperation, which has been pledged by both agencies to provide more monitoring data. Finally, we can better define dietary intake, and not only of the average American consumer, but also consumers in various regions around the country, or those of ethnic backgrounds who consume more food and water containing high residues. That work is currently in process, but we realize that we can't wait to develop definitive information on EDB residues before proceeding to estimate risks. We have asked for as much of this additional data as available by the end of this month. Since we are in the midst of collecting and analyzing the information necessary for risk estimates, I do not want to circumvent that effort by merely guessing at the significance of the residue levels currently being reported. However, I can say several things about our general understanding of the risks of EDB residues in grain products.

The decision to cancel the grain uses of EDB is based primarily on concern for the risks of cancer evaluated for a lifetime of dietary exposure. Since we intend to cancel virtually all agricultural uses of EDB, we expect over a finite period of time—say 5 years at the outside—exposure will decline and then cease. Even if EPA suspended the grain uses of EDB today, many treated commodities would remain in these channels of trade for a period of some years.

It is possible that certain agricultural practices and manufacturing processes can reduce residues in treated grain. We are receiving information from the Department of Agriculture and the food processing industry which will shed some light on this dissipation of EDB residue before the grain even enters the food processing chain.

Let me turn now to the problem posed by EDB contamination of ground water, which has occurred not only in Florida, but in other States. The problems posed by ground water contamination are similar in terms of potential risks, but quite different in terms of the means available for dealing with those risks as compared with grain fumigation. Because of our special concern for ground water, which, once contaminated, can remain so for many years after the cause is removed, we acted to suspend and cancel the uses of EDB which were leading to ground water contamination.

We recognize that any decision we make regarding EDB has significant international economic implications. The EPA has taken several steps to inform other governments of our action and to determine the effects on international trade. All governments worldwide have been notified about our regulatory actions in September and will be kept informed of future developments to insure that any adjustments and reactions by those governments are based upon a sound understanding of the facts.

In conclusion, we believe that the appropriate long-term solution for EDB is to eliminate public exposure by ending the pesticidal uses of that chemical and we have taken regulatory actions to do that. We are now gathering the information needed to assess current levels of public exposure and to determine what actions, if any, are appropriate to insure the public health is protected during the time needed to eliminate the use of EDB and its residues from the food supply.

Thank you for this opportunity to present my statement. This concludes my statement, and I will be glad to answer any questions that you might have either now or after the other panel members finish.

Senator HAWKINS. I would like to ask you now.

As for the record, what is your background and how long have you been working at the EPA?

Mr. JOHNSON. I have a background in economics and public administration, and I have been with the Federal Government for 25 years, mostly in the areas of environmental protection, water supply, water pollution, and pesticides.

I came into the EPA in 1970, with the water pollution program, and have been in my current position as Director of the Office of Pesticide Programs since 1975.

Senator HAWKINS. Since that time, have you been involved in any other major pesticide controversies at the EPA?

Mr. JOHNSON. Yes; I have been involved in almost every one. I started with EDB in 1972.

Senator HAWKINS. What positions did you take?

Mr. JOHNSON. Well, we have taken a variety of positions. In some cases we have taken very strong action, such as the case of 2,4,5-T, in which we emergency suspended the day before the airplanes would have been taking off to spray forests in the Pacific northwest, and that was because of our concern about textradioxin. We have canceled a number of chemicals that have been shown to have risks of the same order of magnitude and even somewhat less than those we believe are posed by EDB. Of the 40 or so suspect chemicals that we viewed over the last 5 or 6 years, we have completely canceled the uses of about a dozen. As I mentioned, we suspended the use of 2,4,5-T. For the remaining chemicals that we have reviewed that were on the suspect chemical list, we have retained some or all of the uses.

As the Senator well knows, we operate on a risk-benefit basis. and all of our decisions are made on the risks and the benefits of each use of a pesticide chemical. We believe that we have operated in a fashion that demonstrates an adherence to these principles.

Senator HAWKINS. So, for the record, we have established that you have been closely involved in major controversies where we have had pesticide concern.

Mr. JOHNSON. That is correct.

Senator HAWKINS. The EPA is expected to establish tolerance levels or guidelines for the level of EDB in the next few weeks. How do you determine tolerance?

Mr. JOHNSON. First, as I said, all decisions require that we review the risks and the benefits of the pesticide or consumption of the foodstuffs, and we will be looking at the levels of pesticide residues that one would expect to find in the various commodities, which I discussed in my testimony, and calculating the risk that would be associated with those levels. Simultaneously, we will be assessing the economic impact of imposing those levels, how much of the food supply will in fact not be able to be consumed, but will be diverted because it will be considered adulterated. We will then balance the risks against the benefits so we maintain an adequate protection of the public health without causing unnecessary economic disruption.

There are two aspects to this: One is the use of the pesticide, which we have already taken action on, on a risk-benefit basis, and we will be reviewing to see whether further regulatory action is necessary on the uses that are now under appeal. The second aspect of the risk-benefit assessment is to examine the risks and benefits of consuming foods which have already been treated and are now working their way through the system. Those are short-term exposures. When one looks at the entire history of the use of EDB, the next few years is only a short part of the total exposure, so we consider the exposure in the next few years to involve short-term risks that we will be balancing against possible disruption in the food supply over the same time period.

Senator HAWKINS. There have been several articles written about how we should be using something else.

Are any of these alternatives safer than EDB and have you adequately tested them prior to allowing their usage?

Mr. JOHNSON. There are a number of alternatives to EDB for most uses. In the grain area, there are four or five alternatives which are available for stored grain. Perhaps the most popular in farm storage where EDB was used is the chemical Phostoxin, which has been reviewed within the last year and found not to pose chronic effects. It's very acutely toxic, but a well-trained applicator or a farmer who is trained in its use can use it safely despite its acute toxicity, and it will not carry over into food supplies and will not cause problems for consumers.

There are two or three other alternatives which perhaps are less desirable that are being used including ethylene dichloride and methyl bromide, and as far as milling machine treatments go, there are a number of chemicals that are also available which have been reviewed by the agency within the last few years and we feel are considerably safer than EDB.

I think when we come to citrus fruits and tropical fruits, I'm afraid we're not in quite as good a position because we still need commercially developed alternatives that are somewhere between the research pipeline and full commercial development. Methyl bromide, which

I understand the State of Florida has begun to use for export to California, is indeed, we believe, a safer chemical than EDB. However, we don't believe that it is the ultimate solution because it does have some problems of its own though it is not as expensive as EDB. The industry is working very diligently to make sure it is only an interim step and is working very hard on cold treatment, which we believe will be an effective alternative in the future and clearly possess no safety hazards, because no chemicals are involved in that particular application.

Irradiation also is another alternative, which is in wide use in the Third-World countries and in many other areas, but has not been fully proven yet in the United States for control of fruit fly in citrus, and this is another avenue that I think will lead to the profitable, successful development of an alternative, but, again, it will take some time. So we do have things on the drawing board, but we are not quite there with respect to citrus and also with respect to tropical fruits.

Senator HAWKINS. Who trains the farmer? You said a farmer well-trained in applying chemicals——

Mr. JOHNSON. Under the Federal Insecticide, Fungicide, and Rodenticide Act, pesticides may be classified as restricted. This means that they can be used only by a certified applicator or under the supervision of a certified applicator.

The U.S. Department of Agriculture and the State Extension Services have assumed the responsibility of training applications and State governments have taken over the responsibility in the majority of cases for actually certifying that the applicator is competent to use restricted-use materials.

Phostoxin, for example, is classified for restricted use because of its acute toxicity and would be restricted to use by those people who had been trained and had been certified by the State to be capable of handling it, be they commercial applicators or farmers.

Senator HAWKINS. They are certified by the State?

Mr. JOHNSON. That is correct.

Senator HAWKINS. Why did you ban EDB as a soil fumigant last September but decided to phase it out for other purposes? Was it because of the financial risk, or what?

Mr. JOHNSON. Well, as I said, we do have a risk-benefit assessment on each use of the chemical. In the case of soil fumigation, we thought that the risks were exceedingly high because as a pesticide used this year, it will work its way down into ground water and remain a source of contamination and exposure for many years to come. With respect to the other uses, the risk is more short term, particularly if you take citrus as the other extremity. The year we stop fumigating citrus, the exposure stops immediately; it does not continue on.

Grain is somewhere intermediate. When we stop the use on grain, it will phase through the system over a period of 3 to 5 years, we expect. However, once ground water is contaminated, people will be exposed to that ground water or we will have ruined a very important natural resource, for perhaps decades. Also, water forms a very large part of a person's intake on a daily basis, and therefore, the dosage from drinking EDB-contaminated water is considerably larger than say consuming some EDB in citrus, which is the other extreme. So that is the reason we felt that the risks were much more significant in the case of ground water, not only today, but over a long period of time.

Senator HAWKINS. State officials have been using one part per billion as its own tolerance level of EDB in foods.

Did the State of Florida contact you before setting that level?

Mr. JOHNSON. I'm not aware of any contacts before the level was set. We did hear about it immediately after it was established. There was some consultation with the Food and Drug Administration, which Mr. Wessel can discuss further, with respect to the applicability of enforcement levels that exist in Federal regulations prior to the establishment of the level, but I'm not aware of any consultation with EPA as to what the exact level might be.

Senator HAWKINS. You stated in your testimony that there is some evidence that food products on the shelves made from grain, containing EDB, has the level of EDB reduced upon baking.

Is there much chance that the mixes, et cetera, that have been pulled off of the shelves would ever be consumed without baking?

Mr. JOHNSON. I don't believe so. The label directions call for some kind of cooking or heating process to take place before they are consumed.

I know some people, including me, might eat raw cake batter or cookie dough in the process of cooking it, but I don't believe I would eat a whole package that way.

Senator HAWKINS. Has EPA—as the leading Federal agency in this controversy—learned anything from this experience that would prevent similar occurrences in the future?

Mr. JOHNSON. Well, I think we have learned some things about our own process. For example, we have learned about some new areas which we ought to monitor and some new kinds of data that we ought to look at before approving a pesticide in the first place.

I think, second, we need to find ways to work more closely with the States to get more current and better information for regulating purposes than perhaps we have in the past.

We have good relations, I believe, with the State of Florida and other States with respect to pesticide misuse enforcement and applicator certification and training, which I mentioned earlier, and I think it should be possible for us to easily extend that a little bit further into the area of helping to monitor more fully our environment in our food supply.

Senator HAWKINS. Does EDB volatilize in water from your well if you were to boil it?

Mr. JOHNSON. We don't have data on that. There are some people that believe it would and others that don't.

I think the most effective way of removing EDB is probably to use activated carbon, which removes not only EDB, but a large number of other organic compounds.

Senator HAWKINS. On each well?

Mr. JOHNSON. It would be possible to put this on each well. Generally speaking, it's more practical and cheaper on a large-scale basis on a municipal water supply.

I think the other alternative is to modify the source of water and use alternative water services to the extent possible. That's clearly another alternative that could be practiced in a water-rich area.

Senator HAWKINS. As the leading professional from EPA, what advice would you give to the people of Florida about drinking water that may contain EDB?

Mr. JOHNSON. Well, we believe that the State program, which has tried to cap the level at a tenth of a part per billion appears to be a reasonable approach. The risk, perhaps substantial, is not outrageous, and the wells will in fact come down over time. and the risks that we have been talking about are calculated on a lifetime basis. We don't have a very good estimate of how long it may take.

There are two factors that apply to risks from the ground water: First, the water moves, so that the point of contamination moves through the underground aquafilter and, second, EDB decomposes over a period of years into other compounds.

So I think for the short term reducing of the levels, either through carbon filtration or closing wells that are above a tenth of a part per billion seems to provide adequate protection.

Senator HAWKINS. What about eating the food products, the grain products, that have EDB in them? What advice would you give people about the grain products?

Mr. JOHNSON. Well, in looking at the figures that we have got, as I said in my testimony, it's just a shade too early to make a really hard conclusion of what residues on the average in peoples' diets, but from what we have seen so far, it appears that the levels we are finding are lower than we predicted would be found in our September 1983 technical documents. We believe that the long-term exposure is decreasing because of the actions we have taken. The major part of the risks have occurred over the last 35 years and we are on the downside of the risk curves now by phasing out remaining EDB uses. I think also that at the average levels, because we're concerned about chronic effects, that the hazard we have seen from consuming grain-based products is not unacceptable over the long term. And, also, I would not worry about an individual package of cake mix or pancake mix that is high. We are not talking about acute effects there. It has to be looked at in context of all of the other levels that people are consuming and other grain-based products.

In looking at, for example, the State of Florida data, which was not randomly selected, as best I can tell, two-thirds of the samples are negative and one-third are positive and at varying levels. If we can get some of the high levels out of the grain and out of the flour, I think we will provide an acceptable level of public protection, but those are the numbers that we will be looking for in the short term.

I think what I can say about the grain situation is that it's a cause for concern and it's a cause for positive action to reduce those levels as quickly as possible. But I don't believe it's a cause for hysteria or panic.

Senator HAWKINS. Does your advice about food and water consumption change when you talk about infants? I understand that the smaller you are, the more vulnerable you are to chemicals in your body. Would that be correct?

Mr. JOHNSON. With respect to this particular chemical, we believe that young people and infants might be more at risk if they begin to ingest EDB than people that are older in terms of the incremental risks of a couple of more years of ingestion, and that's based upon the fact that in the animal studies, tumors developed very early in most of the animals and they never lived out their lifespan because of that. And, therefore, had they lived longer, and infants will live for a very long period of time, the opportunity to develop tumors becomes greater. That's the kind of adjustment we see as necessary. This is a matter of some scientific discussion as to whether this was an appropriate adjustment or not. But, certainly, it is one of the considerations in deciding whether to take more stringent regulatory action on the grain use, because we can reduce the period of exposure to youngsters by 2 years by not allowing the use to continue as we go through the hearing. That's one of the factors that we are trying to take into account.

On the other hand, when you look at the kinds of foods that might be consumed by very young infants, formulas, and the baby cereals, and things of that sort, we are not finding EDB residues. There is a possibility or high probability that the exposure is also less to that age group, but, again, that is another question that we are trying to address through better definition of dietary intake and better definition of what residues actually are showing up in food and we expect to have those analyses done for you quickly.

Senator HAWKINS. In conclusion, how much EDB are the people of Florida exposed to?

Mr. JOHNSON. I have to look at my reference notes for that.

We believe that on the average, people are exposed to about five parts per billion in their diet from grain products, and somewhat less than that through drinking water, and a very small proportion through imported citrus, primarily because local citrus here is not generally fumigated for State consumption.

Senator HAWKINS. Did you say that the five parts per billion in grain products dissipates upon cooking?

Mr. JOHNSON. No; this is what our guesstimate is of the average that you take from grain products, assuming that cooking has taken place; this is after the cooking reduction has taken place. And this number is substantially lower, I might add, than what we had presumed in our technical document, where we presumed that the intake from grain would be anywhere from 30 to 35 parts per billion on the average.

Senator HAWKINS. In your opinion, how dangerous is that 5 parts per billion exposure?

Mr. JOHNSON. Well, we now think it's more on the order of 5 and possibly lower based on actual monitoring in cooking studies that have taken place over the last 3 months.

As I said earlier, this is not the kind of situation we would not like to see continue for a long period of time and we're trying very hard to reduce it.

On a risk basis, I guess it's on the order of probably 1 in 1,000 to 1 in 10,000 increase in probability of cancer in a lifetime and we think that that is an unacceptable level, but, again, unacceptable in the long-term sense.

Senator HAWKINS. Why did it take 35 years to find this information?

Mr. JOHNSON. Well, when EDB was put on the market in the late 1940's, science had not progressed to the stage that it has today and people worried mostly about acute toxicity and whether the pesticide was efficacious in controlling the pest. It was not until probably the 1960's that people began to think about chemicals as cancer-causing agents. And it wasn't until the 1970's, mid-to-late 1970's, that EDB was confirmed to be a potent cancer-causing agent in animals. During the same period, there was a similar evolution in analytical chemistry in the late forties up to the late fifties and EDB could only be monitored at a level of one-tenth per million as compared to parts per billion and trillion that we could find today.

It also is a volatile material, so because they couldn't find it in food commodities in parts per million, they presumed it was not there.

So there were two problems: The people not knowing this was a carcinogen and people presumed it was not there because they could not measure it with the techniques of the day. And really in 1970, analytical methods got better and cancer-causing potential was found, and that's when we began to get concerned about it and began to relate it to——

Senator HAWKINS. It's not being manufactured any more, is it?

Mr. JOHNSON. Well, it's being manufactured for other purposes. Its primary use in the United States is a fuel additive to leaded gasoline and about 90 percent of the production goes into that. About 10 percent went into pesticides.

Major manufacturers, I understand from hearsay information, have stopped production, but there are still stocks in channels of commerce with formulators or distributors which can continue to be used for the nonsuspended purposes, which have been appealed in the judicatory hearing.

Senator HAWKINS. Thank you very much, Mr. Johnson.

We will now hear from John R. Wessel, scientific coordinator for the Office of the Associate Commissioner of Regulatory Affairs of the Food and Drug Administration.

## STATEMENT OF JOHN R. WESSEL, SCIENTIFIC COORDINATOR, OFFICE OF THE ASSOCIATE COMMISSIONER OF REGULATORY AFFAIRS, U.S. FOOD AND DRUG ADMINISTRATION

Mr. WESSEL. Thank you for this opportunity to discuss with you the responsibilities and activities of the Food and Drug Administration regarding the pesticide ethylene dibromide, EDB.[1]

In my testimony, I will briefly review the following three main points: First, the Federal system of laws for regulating pesticides; second, the current regulations governing the presence of EDB residues in food and; third, results of FDA surveillance of various foods for residues of this pesticide.

The use of pesticide chemicals in the United States is governed by the Federal Insecticide, Fungicide, and Rodenticide Act, which is administered by the Environmental Protection Agency. Under this law, a pesticide, prior to its distribution and use within the United States, must be registered with the EPA based on a showing that the pesticide is effective for its intended use and will not result in unreasonable, adverse effects on man or the environment. Additionally, EPA has the responsibility under the Federal Food, Drug, and Cosmetic Act to set tolerances or legal maximum allowable limits on the amount of residue that safely remain on food from the registered agricultural use of a pesticide. Pesticide residues may also be exempted from the requirement of a tolerance when the total quantity of the pesticide on food will involve no hazard to health.

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[1] See p. 66 for the prepared statement of Mr. Wessel.

The Food and Drug Administration is responsible for enforcing those tolerances except for meat and poultry, which is the responsibility of the U.S. Department of Agriculture. In carrying out its responsibilities, FDA samples and tests food for various pesticide residues. Food found to contain a residue in excess of tolerance or for which no tolerance or exemption from a tolerance has been established is considered adulterated and would be subject to FDA enforcement action, such as seizure, when the food commodity is shipped in interstate commerce.

FDA's regulatory position regarding the presence of EDB residues in food is, therefore, determined by the tolerance regulations currently in effect for this pesticide. One of the regulations exempts the organic chemical form of EDB residues from the requirements of a tolerance when they result from post-harvest use of EDB on various grains. By law, this exemption also extends to organic EDB residues that remain in food processed from treated grains. In other words, the regulation means that foods, such as corn products, flour, and cake mixes, could contain any amount of organic EDB residues and would not be in violation of Federal law.

This tolerance exemption regulation was issued by FDA in 1956 when the agency had the responsibility for establishing tolerances for pesticide residues in food. The tolerance exemption was originally granted based on evidence at that time that EDB would be dissipated during the processing of grains and that residues would not be present in finished foods ready for human consumption. It was not until the late 1970's that analytical methods became available that demonstrated that EDB residues could be present in finished food products. Around that time, studies also showed that the organic form of EDB was carcinogenic and could cause other toxic effects.

Around that time is also when FDA began to monitor food for EDB residues. Initially, in 1978, FDA conducted a survey consisting of 570 samples of fruit, vegetables and peanuts for residues of EDB that may result from soil fumigation use. EDB residues were not detected in any of the commodities sampled. However, the FDA limit of determination at that time was approximately 20 parts per billion, which has improved somewhat since then—it's now down to approximately 1 part per billion.

In 1979, we began to monitor for residues of EDB that could result from post-harvest treatment. Of the approximately 200 samples tested in the next several years, beginning in 1979, only 31 were found containing EDB residues at levels ranging up to 3,000 parts per billion in unprocessed wheat. One sample of raw milo grain was found to have EDB at a level of 38,000 parts per billion.

At EPA's request FDA conducted a survey in 1981, which consisted of 219 samples of citrus with a history of known post-harvest EDB treatment. Ninety-eight percent of the citrus samples tested were found to contain EDB residues. The highest level detected was 14,000 parts per billion, which was found in imported tangerines fumigated at the port of entry where FDA collected the sample.

More recently, we carried out a limited survey of bread, flour, milk, and infant cereals collected randomly from various parts of the United States. Four samples of flour were found to contain EDB residues ranging in levels from 2 to 8 parts per billion. All the other samples contained no detectable residues, at a detection limit of approximately 1 part per billion.

In November, when we were alerted by the State of Florida officials regarding their findings of EDB residues in processed foods, the agency collected samples of the same types of foods to determine if they were in compliance with current tolerances for inorganic bromide residues. All results fell well below the tolerance levels. Additionally, the State of Florida provided FDA with duplicate samples of processed food that the State's Agriculture and Consumer Services Laboratory found to contain organic EDB residues. FDA analytical results confirmed Florida's findings.

Last week, FDA issued priority sampling assignments to its field offices to collect samples of imported and domestic citrus and citrus juices for organic EDB analysis. In this survey, positive EDB findings in whole-fruit samples will be followed by a separate EDB analysis of the citrus peel and the edible pulp. This determination should permit EPA to make a more accurate assessment of actual dietary exposure to EDB from treated citrus.

Additionally, we are currently conducting a study developed in cooperation with EPA to determine the fate of EDB residues on cooking processed grain products. This study is intended to validate other studies, which indicate that EDB residues decrease substantially when subjected to normal cooking temperatures. The results of the study should be available to EPA later this week.

Finally, FDA scientists are working with EPA in compiling all available EDB monitoring data, including the results obtained by the State of Florida's testing activities. This priority effort is aimed at developing a base line for updating EPA's estimate of the level of dietary exposure to EDB which, in turn, is to be used by EPA to reassess the level of risk that might be associated with current levels of EDB in the food supply.

Thank you, Madam Chairman. That concludes my formal statement. And I will be more than happy to try and answer questions that you may have.

Senator HAWKINS. What are your personal responsibilities in the FDA?

Mr. WESSEL. I have been with the Food and Drug Administration for almost 22 years. I am a chemist by education and for about the past 12 years, I have worked in the Commissioner's Office of Regulatory Affairs. My primary role has been the development and coordination of FDA's regulatory policies as they relate to pesticide residues in food. As part of this activity, I am responsible for liaison with EPA on pesticide matters and Mr. Johnson and I serve as principal contacts between the two agencies and, particularly, during the EDB problem, which has required almost a day-to-day contact.

Senator HAWKINS. According to your testimony, EDB is found in only a small percentage of the grain products throughout the country.

To what do you attribute this?

Mr. **Wessel.** I believe that EDB, like other pesticides, are used on an as-needed basis, and in some parts of the country and certain times of the year, there probably is not the kind of pest problem that would warrant the use of EDB, so, therefore, it is not unexpected that shipments of grain are found to contain no EDB residues. For example, as summarized in my formal statement, FDA did a survey last fall of mills that were processing grain, and the part of the survey, we tried to find out what the practices at the mills were regarding the use of EDB. We found that most of the mills do use EDB occasionally for spot-fumigation purposes with most of this occurring during the summer months when they have insect problems. In the wintertime, while they are in operation, ordinarily, you would not expect to have an insect-control problem to require the use of EDB. So I think the weather conditions in different parts of the country help to determine whether EDB is needed at any point in time.

Senator **Hawkins.** Does Florida have a higher percentage of food with known EDB than other States?

Mr. **Wessel.** The FDA monitoring data up to this point, can not be broken down according to individual States. Most of our attention up to this point has been directed at trying to get a handle on certain raw products as to where EDB may be occurring and how it may be used. We have not done the kind of extensive surveys that the State of Florida has done on finished food prducts, products ready for or on sale in retail stores. So I would say that Florida has probably the most extensive data in that area, whereas FDA has very little data.

Senator **Hawkins.** With the new technology which we have discussed this morning, it allows us to test chemicals in the parts per billion.

What are your thoughts on this?

Mr. **Wessel.** In 1956, when FDA issued the regulation exempting EDB from the requirement of tolerance, the technology at that time was such that we could not detect for the low levels that we are able to measure today. I think any chemist in 1956 would probably think it is impossible to detect a chemical residue at a part-per-billion level. Today, we are doing it as a matter of routine. It does require a high degree of expertise and competence and certain quality control steps are necessary to insure that you are not finding false-positives, but overall our capability is very good in terms of detecting low amounts of residues. I would not, because of past experience, predict this as low as we could ever go in detecting substances like EDB. Maybe in 5, or several years from now, we can detect levels in the part-per-trillion range. Hopefully, by then, the chemical will not be in use.

Senator **Hawkins.** Did the State of Florida call you initially? Is that how you were notified of the problem here in Florida?

Mr. **Wessel.** Yes; the State of Florida advised us of their findings of EDB in various finished food products, and at that time, they asked for our regulatory position for these findings. This request was in the form of a telegram from the Florida Commissioner of Agriculture, Doyle Conner, to the FDA Commissioner. He responded to that telegram also in writing, that our position was based on the tolerances in the Code of Federal Regulations that were in effect at that time and still are in effect. The guiding regulation regarding EDB in grain-based products being sold in retail stores is the exemption regulation, which essentially ties FDA's hands. It is an impediment to any kind of Federal enforcement since the law says quite clearly that the residues of this chemical are exempt. This was what we informed the State of Florida and that, from the Federal level, there was nothing that we could do.

Senator HAWKINS. Why is that?

Mr. WESSEL. Well, the regulation is a matter of law. FDA followed a formal rulemaking process back in 1956 and, again, as I indicated in my testimony, Senator, the regulation is quite clear. It says that EDB residues—and we are talking about the organic form of EDB, the chemical form, which presents the most concern from a safety point of view—are exempt from the requirements of tolerance. The reason for that exemption was that evidence at the time it was issued, before certain improvements in technology and science, indicated that one, you should not expect to find any residues of EDB in food because the chemical dissipated rapidly.

And, again, as I mentioned in response to your other question, our technology was such that we just did not expect to find low levels of EDB residues in food. We did not have the technology to test for it.

Second, FDA had no evidence to indicate that EDB was a carcinogen and that was not known until the mid- or late-1970's.

Senator HAWKINS. What is being done to correct this situation?

Mr. WESSEL. Well, I think Mr. Johnson has already outlined the course of action that has been initiated by the EPA, and those steps that are still being considered in terms of possible suspension of EDB and the possible revocation of the EDB exemption regulation to remove the impediment to Federal enforcement. And as part of that action, EPA is also considering the establishment of some type of limit that would be suitable for determining acceptable amounts of EDB in various grain-based products, both raw foods as well as processed foods.

Senator HAWKINS. Would you agree with the statement that in testing for parts per billion, it makes a difference which lab has done the testing, because testing methods influence the results?

Mr. WESSEL. Generally, if laboratories that have been in business of doing residue analysis have trained people and exercise the right kind of quality control, you can expect good agreement between laboratories. This is true, in the case of the FDA laboratory in Atlanta, which serves this area. We generally get very good agreement between our analytical work and the State of Florida's laboratory.

The other factor that can influence analytical findings is the methodology that one uses. There are several different methods that can be used for testing different kinds of foods for residues of EDB. But even when we had two different laboratories using two different methods, there was good agreement between the two labs.

Senator HAWKINS. I understand that the State of Florida provided you with 10 out of 80 of its testings.

Do the results of your own studies corroborate or disagree with any that the State of Florida gave you?

Mr. WESSEL. Let me take a moment to find these results. I think it was back in late December that the FDA and EPA and the State of Florida wanted to make certain about some of their analytical findings. We received from the Florida lab 10 samples of food that they had previously analyzed and found EDB residues. These samples were then analyzed by our laboratory in Atlanta.

Of the 10 samples, 6 showed very good agreement, almost identical results. The results from the 4 remaining samples were, in all cases, much lower than the State of Florida's findings.

I think this difference may be attributed to several factors: First, I do not think we had any guarantee that we had what would be considered a true duplicate sample. The sample results that Florida obtained were conducted much earlier than we received the sample. And in the situation where you have drawn samples at different points in time, I am not sure if you can say that the sample is the same as it was several weeks before. This is particularly true in the case of EDB, which is volatile but perhaps not as volatile as we originally thought, but it is volatile and in time, there may be some loss of the residue. Therefore, I do not believe it should be surprising that at least generally some of these samples were found by FDA with results lower than those originally reported by the State.

Senator HAWKINS. Mr. Johnson seemed to think that the water problem was more severe than food. What is your opinion?

Mr. WESSEL. In this case, FDA has not been doing any EDB-water monitoring. This again is the responsibility of the EPA and its part of their mandate to evaluate the safety of pesticides. That mandate does include water, so that there is very little that I or anyone from FDA could add to Mr. Johnson's statement regarding that aspect of the problem.

Senator HAWKINS. Thank you, Mr. Wessel. Thank you for coming down here today.

We would like to now hear from Karen Darling, Deputy Assistant Secretary for Marketing and Inspection Services for the USDA.

## STATEMENT OF KAREN DARLING, DEPUTY ASSISTANT SECRETARY FOR MARKETING AND INSPECTION SERVICES, U.S. DEPARTMENT OF AGRICULTURE

Ms. DARLING. Thank you. As you have heard, our USDA statutory authorities in this matter are very limited; they are limited only to meat and poultry inspection. However, we do take our public health responsibilities very seriously, both in the protection and safety of the food supply for consumers and producers.

The first Federal pesticide act was passed in 1910. It's intent was to protect farmers and ranchers from adulterated or misbranded products. Now, some 75 years later, certainly the responsibility has expanded to include reducing the risks to mankind and the environment. So things have changed a great deal during the years.

I would like to just talk a bit about agriculture in general.

This State has a great citrus industry and we export a great deal of citrus from Florida. The immediate suspension of EDB for citrus products could cause a great marketing and economic disruption to this fine industry. In other words, Florida is a State that is wheat deficit. I get worried when I think of a marketing disruption. We could have an intercountry sort of trade war, where some States won't take your citrus products if you won't take their grain products. I don't think that is in the best interest of anybody concerned—the Government, the consumers or the producers. I am fully convinced that EPA will act in a responsible manner and not do something precipitously that would cause a marketing or trade war either internationally or domestically.

We have come so far in our scientific ability to detect pesticides, but somehow science and the law haven't been able to keep pace.

We have met with the Russians; we have met with the Japanese, with many of our international trading partners over the flack on EDB, to see where we should go from here. The scientific and technical community throughout the world is endeavoring to provide more data on the future of all chemicals, not just EDB.

We require so much of each other, such as our not permitting citrus products to enter this country unless they have been treated. Three methods have been approved for treatment: One is high vapor heat. It is an energy-intensive method by which high temperature steam is forced through a container. It's very expensive, although I'm not sure what the cost would be. I don't believe we have more than one or two facilities available to do such in this country. The other one that Ed Johnson mentioned is cold treatment, but we're not sure that every citrus fruit or every tropical fruit can endure the temperature and time manipulation. Cold treatment currently requires storing fruit 7 days at 60 degrees plus 10 days at 34 degrees. The USDA continues to seek a viable, nonchemical fumigation method. Florida doesn't want Mexican fruit flies; you don't want melon fly; you don't want the famous Mediterranean fruit fly any more often that it arrives on its own. The rest of the world doesn't want Carribbean fruit fly, which we have in Florida. So in order to guard against trading our destructive fruit flies with each other, we have required treatments.

EDB has probably been the most effective fumigant we have ever found for citrus. It goes right through the peel and into the pulp of the fruit, killing the larvae. The one thing nobody wants to import is the fly. The U.S. Department of Agriculture probably has the most strict border enforcement of any country in the world in trying to prevent destructive plant pests and/or animal diseases from entering our country. We take this as a public health responsibility. And by doing so, other countries also put restrictions on this country. Most countries use EDB, and during the Medfly crisis about 3 years ago, the Japanese required fruit coming out of this country to be fumigated with EDB.

There are international protocols in place to make sure that we all are exporting clean products. We have also found that our trading partners would rather have a clean product than a product infested with destructive pests such as might be found in grain, particularly, flour.

Our best estimate at the Department of Agriculture right now is that probably less than 5 percent of the grain has been treated with EDB. We took EPA very seriously when it decided to suspend and cancel the agricultural uses of EDB. From what our millers tell us, our growers and our grain companies, there is very limited use of EDB. We hope to have a phaseout while other alternatives are being sought.

There are some grain fumigants that are not yet registered by EPA which some of our foreign trading partners would prefer that we use rather than, say, methyl bromide.

From an agriculture standpoint, we look toward the marketing disruption which would be caused by percepitous action on EDB as much as we look at the public health aspect. We've been using this chemical since 1948. It has to be a chemical that will become the most studied subject since DDT. We're working with EPA through the Agriculture Research Service at the cooking level. I'm more concerned with what you as a consumer might ingest at the point of consumption if there is residue than what might be found in the elevator.

In our first 30 samples of grain from export elevators, 21 samples had zero residue and the highest was 22 parts per billion in wheat.

Within a week, by next Monday, we will submit to the EPA, results from 200 samples of wheat and 200 samples of corn. There has been some feeling that corn is probably at a higher residue level than wheat. There is also some speculation that the Southern part of this country would find a greater concentration than maybe the North. We have tried to help EPA come up with a good data base upon which to help make its very difficult decisions, and outside of that, I would be happy to answer your questions.

Senator Hawkins. As a consumer who eats oatmeal every morning for breakfast, do I have to be concerned about eating oatmeal?

Ms. Darling. I wouldn't think so. You cook it.

Senator Hawkins. We have had some interruption, as you know, in the marketing of a lot of these products.

I get constant telephone calls on our 800 number in our office as to what should they do and not do because it has not been determined what level is tolerable to the body. Can we be sure that animals eating this grain that you are talking about don't transmit EDB to human beings?

Ms. Darling. Senator, the 330 samples that we took last August from the fat of meat products and poultry products showed only one bore sample with a very low residue of EDB—just 3 parts per billion.

Our intent is to do more random sampling across the country. We have 9,000 meat inspectors out there and they could very easily pull fat samples and test for EDB. It hasn't been on our list of things to test for until recently, but we have started a continuous random sampling procedure for EDB in meat and poultry.

We also did a sample on eggs and egg products, and found nothing significant to report whatsoever.

Senator Hawkins. Some estimates place over 50 percent of our U.S. grain currently in storage as having been exposed to EDB.

If this is true, what is the market value of that grain at today's prices?

Ms. Darling. Well, Senator, there isn't much agreement on how much grain has been treated with EDB. The USDA thinks treated grain is more in the neighborhood of 5 percent. And, yet, we don't have that good a handle on it.

Today is the day that the quarterly storage report comes out to tell us just how much grain is being stored. But by the time you deduct fed grain and add new stocks, the numbers stay somewhat the same. We had the two great grain crops back to back. Then our PIK program helped cut back on stocks last year. With the cutback in the use of EDB, and a greater use of 80/20, a carbon tetrachloride and carbon disulfide combination, by the grain industry, I don't believe we would find much more than 5 percent treated grain stocks. And as far as a dollar number, I can't even hazard a guess.

Senator HAWKINS. Would the Federal Government be responsible for reimbursing farms if they recall the grain?

Ms. DARLING. That would be EPA's problem. I seriously doubt there will be any recall of raw commodities.

And I hate to throw this one in, but it's kind of trying to eradicate avian influenza in Pennsylvania. The Federal Government pays the replacement cost of the bird through indemnity. It's very expensive.

Senator HAWKINS. You heard the testimony here today, I'm sure, and you have discussed it with the proper official, that some suggest methyl bromide as an alternative to EDB for grain and citrus. What do you feel about that?

Ms. DARLING. Well, we're not sure that methyl bromide is going to be the solution. If it all proves out that the bromide part of EDB is the dangerous substance, I think we would be a little presumptuous to think that methyl bromide would be the replacement.

I think we should continue to look for nonchemical substitutes as best we can. I don't find any great enthusiasm for looking at any bromide product right now.

As far as irradiation is concerned we must wait for FDA to make its proposal. A hundred K-rads had been approved during the Med fly crisis, but that has elapsed. So, irradiation is not a viable alternative quite yet. I think we are going to have a little problem with irradiation should it be approved because it will be an expensive process. I don't envision the Government building an irradiation chamber. I know that the industry won't decide to commit resources toward this process until the FDA has given the go ahead to look at the irradiation of fruit products.

Senator HAWKINS. What other countries use EDB?

Ms. DARLING. I have a whole list here, and this is not a complete list, but it's as far as we know.

Haiti, Venezuela, Jamaica, Guatemala, Barbados, Costa Rica, Santo Domingo, Panama, Colombia, Mexico, San Salvador, and Honduras. Also Argentina, Australia, Belgium, Czechoslovakia, Finland, Germany, Hong Kong, India, Japan, Kenya, the Netherlands, New Zealand, Singapore, South Africa, Sweden, and the United States.

Senator HAWKINS. Your meetings with the representatives from Japan on this chemical, what did Japan say about it?

Ms. DARLING. Well, Japan is totally dependent on importation of grain products, and for the most part their citrus products. They are taking more of a wait-and-see approach to what EDB levels are set and what the U.S. Government decides to do about it overall. We export approximately two-thirds of the grain produced in this country. I hope we don't jeopardize that.

Senator HAWKINS. What effect will the banning of EDB have on both domestic and foreign products if the other countries continue to use it?

Ms. DARLING. We import very little grain product.

We import quite a bit of tropical fruit, mainly mangos and other fruits. A prohibition could cause some major marketing disruption.

Senator **Hawkins**. Do you have any personal feelings what the safe tolerance level should be?

Ms. **Darling**. The USDA, like the State officials here and like our sister agencies, also has a scanty data base. I think we would be remiss to make a recommendation to EPA on how levels could be set without a better data base. We have better information on citrus than we do for grain products and all such data has been submitted to EPA.

Senator **Hawkins**. How dangerous do you feel that the exposure is?

Ms. **Darling**. Personally?

Senator **Hawkins**. Yes.

Ms. **Darling**. I'm not worried at all. I think it was summed up for me when a nice lady called and asked me if there was EDB in her cigarettes.

Senator **Hawkins**. We thank you for coming and I hope that you enjoyed your stay in Florida.

Ms. **Darling**. Thank you.

Senator **Hawkins**. Let's go on to panel No. 2.

This is panel No. 2, and this is Sherwin Gardner, vice president, science and technology of the Grocery Manufacturers of America, Inc.

## STATEMENT OF SHERWIN GARDNER, VICE PRESIDENT, SCIENCE AND TECHNOLOGY, GROCERY MANUFACTURERS OF AMERICA, INC.

Mr. **Gardner**. Good morning, Madam Chairman. I am Sherwin Gardner, vice president, science and technology of the Grocery Manufacturers of America, and with your permission, Senator, I have a statement which I will submit for the record,[1] but I would like simply to summarize it for you. The GMA is a trade association representing the leading manufacturers of grocery products in the United States. Membership of GMA is composed of 130 companies which employ over 2½ million people and account for over $200 billion in total annual sales.

On a personal note: Prior to joining GMA in 1979, I served as the Deputy Commissioner of the U.S. Food and Drug Administration for 7 years.

GMA and its member companies have cooperated with the Environmental Protection Agency in providing it with laboratory data from approximately 1,000 tests that effectively indicates that EDB levels in grain-derived products is substantially reduced through processing and cooking techniques. The data indicate that EDB levels are reduced to such minute levels in food products as consumed that there is no danger to the American consumer.

I would like to submit a copy for the record of the compilation and analysis of these data to the committee.[2] The results of analyzing raw grains from bulk storage show that 133 out of 264 samples analyzed, or 50 percent, contained levels less than 1 part per billion EDB. The median level EDB for the 264 samples is calculated to be less than 1 part per billion. The results for wheat, which represent over 10 percent of the U.S. diet, showed that 47 out of 102 samples, or 46 percent, contained levels of EDB below 1 part per billion. The median level for EDB for the 102 samples is 1.2 parts per billion. These results indicate very low levels of EDB residues in most unprocessed grain. Most importantly, however, EDB analyses were performed on a number of grain-derived products prepared as they are normally eaten and the results indicate that 153 out of 192 product samples, or 79 percent, contained levels of EDB below 1 part per billion. The median EDB level for the 192 samples is less than 1 part per billion.

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[1] See p. 72 for the prepared statement of Mr. Gardner.

[2] See p. 80 for a reprint of the compilation referred to by Mr. Gardner.

A valid risk assessment on the potential risk of exposure to EDB-containing grain products as consumed must be conducted before taking actions to remove products from the marketplace. We believe that the risk assessment published by the EPA in its September decision greatly overstates the risks from grain and also some serious faults.

GMA has undertaken a risk-assessment study of EDB in grain-based products and have committed to providing it to EPA.

Our preliminary findings from this work show that existing food products containing minute levels of EDB presented insignificant health risks and, therefore, any actions against grain products are inappropriate and unwarranted.

The GMA and food industry are committed to maintaining the safety and wholesomeness of the U.S. food supply and we will continue to assist EPA and other Government agencies in determining a valid risk assessment for EDB in food products.

Senator Hawkins, that concludes my summary statement. I will be pleased to answer any questions that you might have.

Senator HAWKINS. Thank you. Mr. Gardner, since EDB has been entitled a soil fumigant and is being phased out as a grain and citrus fumigant, it seems to me that EDB exposure is more of a short-term problem in the environment than is generally known, but how long do you see the chemical remaining in our food chain?

Mr. GARDNER. We would agree with you, Senator, that EDB is a short-term product.

Based on the EPA's announcement to withdraw the use and based on the actions that we understand people have already taken, we foresee that EDB should disappear from grain products in about 3 years. And our risk assessment is based on that knowledge and understanding.

Senator HAWKINS. You represent the major food-producing-and-processing companies in the United States which have a great stake in this question: With the billions of bushels of grain and corn that have been exposed to EDB, how can the private sector act responsibly in eliminating EDB from the food chains as quickly as possible?

Mr. GARDNER. There are a number of things, some of which have already beeen done. A number of refiners and millers have stopped using EDB in their operations and have asked their suppliers to do so, also. And some people are looking at their processes to make sure that they are making the most advantage of them in order to produce flour and other mixes and final products so that the EDB has been processed out substantially.

I think the most important part is that, based on the actions already taken, including EPA's announcement of withdrawing, that a risk problem in EDB-containing products is really insignificant.

**Senator Hawkins.** What actions are being taken to reduce the EDB levels contained in the grain currently in storage? I remember testimony from this morning, and things that I have read, that aeration and heat helps dissipate EDB.

**Mr. Gardner.** That is correct. Aeration, heat, and, very often, simply allowing the product to sit will cause a great deal of it to dissipate.

In addition, just the normal handling of grain and flour which has an aerating action will help to reduce the levels of EDB and, I think, that the data we have produced and submitted here, as well as to EPA, demonstrate that is in fact the case.

**Senator Hawkins.** How many other States have tested food products for EDB?

**Mr. Gardner.** I am not certain of the exact number. We do know that Texas, California, and Massachusetts are among those that have reported sampling and testing products for EDB.

**Senator Hawkins.** How many other States have acted to remove products from the shelf?

**Mr. Gardner.** At this point, only the State of Florida has acted to remove products from the shelves. There are no other States that have taken that action.

**Senator Hawkins.** Didn't Texas recall its shipment from a supplier?

**Mr. Gardner.** Not to my knowledge. It may be, but I'm not aware of it.

Texas has been sampling products, but have not removed groceries from the store shelves.

**Senator Hawkins.** Why didn't they take action like Florida?

**Mr. Gardner.** Well, the Texas Health Commissioner reviewed the knowledge about EDB and concluded that it did not present a health hazard, certainly not one that required the State's action at that time. And they are waiting for EPA's review of the situation and will look forward to receiving guidance from them about what action they might take.

**Senator Hawkins.** Florida has been found to have more products with greater concentration of EDB than most of the other States.

Is there, in your opinion, any reason for this, such as the distribution of patterns of certain of your manufacturers? We are a terminal State; we are at the end of the line.

**Mr. Gardner.** I'm not sure that the EDB situation differs in Florida substantially from that which exists in other States.

The analyses that have been conducted in Texas seem to reflect the same sorts of findings with EDB in grocery products, and I'm really unaware that the situation does differ appreciably elsewhere from Florida.

**Senator Hawkins.** I think we found in our State study that the distribution was very high across the top of the State, and that a lot of the products come across the State line into Tallahassee, and over to Jacksonville, moving as far down as Ocala, and those are the storage points for your products and then later they are shipped on to southern Florida but there are found to be higher levels in the northern portion of Florida. What is your opinion?

Mr. **Gardner**. Well, I can only speculate at this point without seeing the data of what you are looking at, but one consideration is that corn mix, where flour is produced from corn, is a much more locally produced and consumed product than flour produced from wheat, and it may be that there is a much shorter span between the time of treatment of corn, and the usage, and marketing of it that accounts for that. A number of the samples that the State of Florida has been looking at are corn-based samples, and so that may be one reason for what you are saying.

Senator **Hawkins**. We found that 32 percent of the tests were positive; 42 percent of the positive samples were in a warehouse in Chipley because of the distribution pattern in Florida.

How much has your organization, the GMA, worked with any Federal, and State, and local governments to reduce the fear that has been generated in both the business community and consumers?

Mr. **Gardner**. As I indicated in my statement, Senator, we have begun a risk assessment to quantify the amount of risk that actually exists and to be able to speak about it subjectively to American consumers. We have also undertaken the analysis of raw grain, flour produced from the grain, and the finished product, and have furnished that report which represents the results of more than 1,000 individual tests.

We are continuing to conduct tests on those forms of grain and grain products and will continue to supply them to EPA so that they can make statements to us and in turn we can also make statements to them, to the American public, the results we have found show that the levels of EDB in consumed products is really low.

Senator **Hawkins**. I'm sure you have learned a lot from this experience.

Do you have any recommendations to make to the Agriculture Committee to prevent future problems of this kind?

Mr. **Gardner**. I think I would like to reserve an answer to that question, Senator, and once we have got our risk assessment completed and have finished our analytical work, why we will be delighted to respond to that question.

Senator **Hawkins**. When were you first notified of the association of the EDB contamination?

Mr. **Gardner**. Well, there are actually two times when that occurred. The first time was back in September when a number of television stations began looking at finished prducts in the grocery stores for EDB contamination.

The second time was more recently in December, responded to Florida's actions to withdraw products from the marketplace.

Senator **Hawkins**. So in summary of your testimony, can you tell me again what you personally feel the risk is associated with EDB?

Mr. **Gardner**. It's more, Senator Hawkins, than a personal assessment.

Our views of the risks are obtained from the analysis of samples in the laboratory and from the advice we have been receiving from a number of qualified professionals who have backgrounds in toxicology and risk assessment.

And, in summary, the understanding and the belief that we have at this point is that EDB in grain products does not present a risk to humans in this country.

Senator HAWKINS. Can you list the source of your scientific data in your testimony?

Mr. GARDNER. Yes; we have retained Dr. Joseph Rodricks, who has had extensive experience with toxicological evaluation and risk assessment first as a member of the Food and Drug Administration, and more recently, as an independent expert in the consulting business.

There are other scientists, one of whom I believe is here this morning, Dr. Friess, who has conducted extensive toxicological research in ethylene dibromide, and his conclusion, and the conclusion of other experts is that there is no real significant risk from those products.

Senator HAWKINS. Thank you very much. We now call on Dr. Friess.

## STATEMENT OF DR. SEYMOUR L. FRIESS, TOXICOLOGICAL CONSULTANTS, ARLINGTON, VA.

Dr. FRIESS. Good morning, Senator Hawkins. With your permission, I will review my testimony as presented and delivered and then open for questions because the issues are scientific; they are fairly complex.[1]

My name is Seymour L. Friess, and to establish my credentials, I am the president of a firm of consulting toxicologists based in Arlington, Va. I have had extensive research in toxicology, pharmacology, chemistry research, and safety evaluation for important chemicals continging on human populations. I am a past president of the U.S. Society of Toxicology, of the American Board of Toxicology, Inc., the principal accrediting board for performance in toxicology research and testing, and I am also a past president of the International Scientific Union of this polyglot discipline called toxicology, that is, the International Union of Toxicology.

You will note that I will deviate from time to time from the prosaic wording of my statement.

Beginning in the late 1980's, my firm of consultants was retained by the Florida Citrus Commission and other interested organizations to conduct studies of the scientific research literature on potential health effects of the important agricultural chemical ethylene dibromide, both in experimental animal test systems and in human populations who have been heavily exposed to ethylene dibromide over many years in the work situation.

Senator HAWKINS. You meant, the 1970's?

Dr. FRIESS. I really meant in 1980. We were retained in 1980. We have been studying the literature and the data basis ever since that time. We have been emerged in EDB since 1980.

Senator HAWKINS. How do you feel?

Dr. FRIESS. Great. As I get to my bottom line, I will indicate only that my appetite has increased and things have happened in the aging process that tell me that EDB has not been a great threat to my life.

So my review of the toxicological and epidemiologic literature, plus the increasing body of available data on human exposure, my colleagues and I and my firm have reached certain conclusions about the ability of this chemical to evoke specific health effects in test animals or humans and its importance now as a function of the exposures or dosages encountered.

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[1] See p. 112 for the prepared statement of Dr. Friess.

As I progress, it will become quite clear that the threat of EDB clearly must be related to the dosage that you encounter or your exposure on a daily basis, the duration of those exposures over time considered as a fraction of your lifetime and the root by which the exposure occurs, by oral ingestion, by water, food, or by inhalation.

Today, I would like to summarize briefly our health-effect observations reducing them as far as I can to clear language, and the circumstances of the scientific observation—in respect to risk assessment in humans—for that health effect which is judged to be the most life-threatening, namely, cancer.

All of our national risk assessment processes to this point have been predicated on looking for the effect called cancer in test animals, and then attempting to deduce by extrapolation to the human species what sums of doses, taken repeatedly over long periods of time, might result in cancer in exposed humans.

The key to the entire discussion will be: What dose, repetitively taken, can or cannot lead to an observed effect?

Toxicological research literature indicates that the major health effect of test animals by dosing for very large fractions of their lifetime, better than half of the lifetime, generally, two-thirds of the lifetime, is cancer. There is evidence for mutagenic potential in compounds in test systems. There is evidence in animal doses at very high levels for impairment of certain indices of reproductive potential in the form of structure of sperm in males, and on male reproductive organs, these are very high dose experiments.

We now go then to the experiments that really count and those are the ones which are high dose in animals attempting to elicit cancer as the observable end point. Before I touch on those, I would note for you that there are at least three studies of potential health effects on human populations who have been exposed occupationally to EDB over long periods.

As we noted earlier, EDB has been made for a long time, a high-volume chemical, much of which goes into gasoline, leaded gasoline, so that there have been workers exposed in the course of manufacture, blending, packaging, construction, and diluting this chemical for many, many years. These worker populations have been studied in a process called epidemiological studies, which the major effect of concern was looking for excess cancer over the course of working lifetime above and beyond that that we are all subject to, just by living and working in this world, namely, a one-third risk of cancer, which is our normal event. The epidemiological studies do have flaws, but they are honest and in common with most epidemiological studies. You can look at the data which are available and you can honestly assess the flaws and come to the conclusion if these, as has been done by EPA in their TD's, 2, 3, and 4, that results are essentially negative for workers who have been highly exposed to EDB in the manufacture, construction, and usage occupations.

However, despite these negative epidemiological results and heavily exposed human population, which is really the test of the pudding, plus a more recent experience in epidemiology which workers were asked about reproductive difficulties of any again, with negative results. We must turn to animal studies for our fundamental data base on which to judge risks in humans, even though we have never seen this effect in heavily exposed human populations. This is a proper procedure, because in human populations, one may have to go to a very large fraction of a lifetime before low doses would begin to show their effect. Therefore, one has to use animal experiments and have high doses to try to elicit the effect to learn something about the dose-versus-response relationship of how the chemical produces cancer in animal models and then to attempt to extrapolate those results; dose-versus-percent response to humans under a variety of assumed exposures. This is the way science operates at the moment to provide a chronic-data base in animal models, which the risk assessor then uses to try to project what the human might experience over the course of a lifetime at very much lower concentrations.

Now, we would note that there are two major so-called bioassays in animal models that constitute our total data base at this point. They were run by the National Cancer Institute. They are both 2-year exposures of rats and mice exposed on a daily basis to very high levels of EDB. The reason for it is that the mission of the National Cancer Institute, which has now been transferred to the national toxicology program and the Department of Health and Human Services is trying to assess the cancer potential of a compound, the chemical, by deliberately forcing high concentrations into animals for long periods in order to assess whether the chemical can or cannot produce cancer under the worst conditions. This is the mission.

This type of experiment is not designed to produce a dose-response relationship for risk assessment purposes, but this is the case that that's the majority of data we have on long-term or chronic exposures, so that we must look to the two experiments which are available done by the National Cancer Institute and one was by intubation or gavage, which means the injection of a chemical on a daily basis by sample tube directly to the forestomach or the rat. The rat has a forestomach as well as a major glandular stomach, and getting a dose in the forestomach of the rat can be done by dissolving the chemical at a high concentration in corn oil and delivering that chemical by stomach tube directly to the stomach with an injection device. That way you know how much to put into the animal. The second device or second way of exposing is to have animals who are daily exposed by inhalation to high concentrations of this very irritant chemical, EDB.

We would note that if you ae going to worry about the use of animal data projected to the human, you have to study the animal in the mode which is most closely related to the way the human is going to be exposed. We're talking today about exposure by eating food with traces of EDB, by drinking water with traces of EDB, so of the two chronic bioassays available for discussion, forming our data base, the one which was the so-called intubation bioassay, where the chemical was delivered in high dose dissolving corn oil to the forestomach of the rat on a daily basis, 5 days a week, for 2 years, which is two-thirds the lifetime of the animal, is the most germane method of exposure.

Now, what I have to report is that the experiment was clearly performed and described in the bioassay and, unfortunately, it doesn't provide a satisfactory data base in which graded doses-versus-graded-responses can be used for risk assessment projections in a human. There are many major flaws in that so-called intubation or gavage bioassay. The dose selection was very poor in the first place. Early deaths occurred in the animals. In order to be a meaningful cancer bioassay, you want the experiment to go on, to be meaningful, with appreciable numbers of animals surviving up to 2 years. Because the dose selection was very high and the chemical is very irritating, animals started dying within the first year of experiment. In desperation, which shows up in the experiment, the investigators changed dosages, stopped them, changed them, restarted them, all in an effort to keep as many animals alive as possible, to get them over the 1-year hump, to try to get to data which would say what kind of cancer can you measure at greater than 1 years' time? The dose selection resulted in so many early deaths, that you could no longer use the experiment as a data provider for a lifetime test. That's the major flaw.

The second is, as I have noted, the dosages were stopped, started, changed, and restarted, so that we really can't relate any cancer incident rate in these animals to any specific dosage. What the investigators did was to lump it all together in something called a time-weighted average dosage of about 40 milligrams per kilogram body weight per day. That dose of chemical delivered by stomach tube did indeed produce cancer; no doubt of it. If a single-dose experiment, however. Next, a very major influence could be spoken to best by the rat. When the chemical is delivered by stomach tube, by gavage, a slug, as it were, reaches the forestomach. This is a highly irritant chemical; it proceeds to destroy tissue in a pathologic way and irritating to boot means that the animal in his normal way would attempt to get rid of that irritant as quickly as possible by ejection through the gastrointestinal tract and, hence, what we don't know, never will, is whether any fraction of the dose that got into the animal, or what fraction of it got into the animal, actually stayed there and what fraction was excreted because of the high irritancy. And, finally, because of that high irritancy, which begins the destruction of tissue in the forestomach and this is where the tumors ended up in this experiment, we really don't know whether the chemical produces cancer or whether the chemical produces irritation and it's the irritation which produces cancer.

For all of these reasons, to a toxicologist, to any fundamental scientist, the experiment is unsuitable for providing the kind of data we need for risk assessment, which is a clear dose producing a clear cancer response.

Now, even the Environmental Protection Agency, in its position to document, recognized this fact and also recognized that the bioassay as run by intubation doesn't even limit what we are interested in, which is the ingestion of traces of EDB in food or water, so they attempted in recognition of the poor modeling, to produce what is essentially a conversion of a poor intubation experiment hopefully into a better feeding experiment, and to do it, they used a rather clever strategy, which is to take an entirely different chemical, called dibromochloropropane, which had been studied by bioassay, by the gavage route, by stomach tube, and also by feeding, to construct an estimate of the cancer potency by those two routes for this new chemical, dibromochloropropane. And then to use that ratio as a correction ratio to try to convert the EDB gavage bioassay into an equivalent feeding experiment.

I think that's a clever stratagem; unfortunately, it has no scientific justification, so we are, therefore, left with whether such data from that public bioassay can even be used in risk assessment. At the risk of boring you—well, let me quickly go through the steps: One; the setting up of animal data. First, you would say: I will take the data which consists really of one average dose producing one kind of cancer early on, in this dying animal population, and I'll fit it to some sort of a linear mathematical equation which relates dose to percentage response.

There are dozens of such equations to be used and any regulatory agency uses the one which is its favorite at the moment. One which has no complaint about this process, it's the state-of-risk assessment at the moment. You take animal data and model it by some equation. You do that for two purposes: One purpose is to be able then to use the equation which has been fitted mathematically with the data from very high dose experiments to try to estimate what would have happened if you had used very tiny doses, because that's what we're interested in. The second step is to then modify this animal-fitted equation to try to make it into a predictive human equation. And the way this is done in general is to say for animal to human, I don't know that that human is susceptible, but I will assume that he is; I will assume that the animal equation holds for him, and at most, I throw in another factor, which is the relative metabolic rate of human beings, versus the metabolic rate of the animal. The reason for this being that, in general, many chemicals develop metabolic activation to produce the active carcinogenic form.

EPA did use that conversion factor, thrown onto the equation, fitted with the very poor rat gavage data.

And third, they have used that equation, for what we have been talking about in the literature, the press, the regular community, and in Congress, for assessment of so-called risks in human beings. I have done nothing up to this point. I have shown you the agony of the set of assumptions which lead you to what you call quantitative risk assessment. At its best, if your bioassay is a good experiment and if you state these assumptions clearly as you move along and what you are going to be doing about projection into the human, you can understand and say that is the best projection we have got; however, I would submit to you when the data base at the very beginning of this process, when the rat bioassays are poor, never intended to be risk assessment, that no matter how many steps of transformation you go through before you project into the human and predict cancer rates for an effect never seen in the human being, you can't transform poor bioassay results into good risk projection.

So that now departing from my text, I would note that where we stand is that we only know that at 40 milligrams per kilogram of body weight per day in the rat treated by gavage, we can produce cancer; there isn't a spread of data in either animal models or humans showing that down at the part per million level, which is a thousand times higher than the part per billion level that we're talking about here in foods, there is no shred of evidence that you can produce cancer in either animal models or human beings.

Indeed, I will cite one other experiment. In 1981 or 1982, an experiment came out which was an inhalation exposure in rats and guinea pigs and other species, showing they, when they inhaled EDB at 3 parts per million, which is base, that is 3,000 parts per billion, for 13 weeks, there was no evidence of tissue damage, no evidence of cancer.

At levels below 3 parts per million, no evidence of tissue damage, no evidence of cancer.

My conclusion, therefore, is, from the little bit of data that we have at low levels in animals, which are negative, from the human exposure, epidemiologically, which are negative, that we really have no cancer worries about the human ingesting EDB in tiny amounts even on a repetitive basis in foods or water over long periods of time.

If I look at the 1 part per billion level established by the State of Florida, I find that that is about one ten-millionth of the dose that produces cancer in the rats by the gavage method.

If you further say that when you cook the food and you lose about 75 percent more at minimum of the data that I have seen of the EDB in raw food, you are down to about one hundred millionth of the dose which produces cancer in that intubation experiment of the rat, which is our only solid data, as faulty though it may be, and that those tiny fractions of daily dose, milligrams per kilogram of body weight per day or micrograms per kilo weight per day, I feel that the risks of cancer to humans even ingesting food at the parts per billion level or higher is negligible; the risk of concern is indeed negligible.

I will be happy to answer any questions.

Senator HAWKINS. Thank you. Can you tell what the study of toxicology is about?

Dr. FRIESS. Yes, ma'am. It is the study of the interaction of chemicals with tissues either in animals or humans to produce some change in either the functional state of the tissue or the structure of the tissue; it's the danger that the chemical will produce an adverse effect in a tissue or a target organ in animals or humans.

Senator HAWKINS. Previously stated from your testimony, you were the president of National Toxicology——

Dr. FRIESS. Past president; now chairman. I was past president of the Society of Toxicology, which is our national organization, professional organization in toxicology.

Senator HAWKINS. Are there any other posts that you have held in your positions?

Dr. FRIESS. Within the Society of Toxicology, I have been chairman of the board of publications. I have been a member of the council of that society. I have been the founding president of the American Board of Toxicology, Inc., which is the major organization in the United States for certification of individuals for the practice of general toxicology, both research and testing. And I am the immediate past president of the International Scientific Union of Toxicology. My duties there ended in 1983.

Senator HAWKINS. Very currently then?

Dr. FRIESS. Very currently my major occupation is the president of a firm of consultants in toxicology based in Arlington, Va.

Senator HAWKINS. As a general proposition, do you think that most cancer tests using laboratory animals are invalid ways to determine whether such substances which are harmful to human beings?

Dr. FRIESS. No, I don't use the word "invalid"; they are model systems to let us get a feeling for dose versus response in the animal. It is that feeling about how high a dose is needed to make what kind of response that lets us at least begin the process of translation or projection to the human. That translation or projection is only one step, though, and one should actually verify those translations and predictions by looking at exposed human populations across the loop to see whether the incident rates that you actually observed for that effect in heavily exposed occupational population, bear up the predictions that you have from animal experiments.

Senator **Hawkins**. You stated in your testimony that you had a study in 1982 of direct exposure to EDB in humans.

Dr. **Friess**. Yes, ma'am. This was published in 1982 and it was the result of a 13-week exposure of rats, mice, and guinea pigs to EDB inhalation in vapor phase at high levels working down to low levels, which is what you want to do, and at 3 parts per million for 13 weeks—this is around-the-clock exposure; that is a lot of exposure—there were no observed adverse effects.

Now, this is not a chronic experiment. It's not the desirable experiment, but it is good to know that those results were negative when looked at at the tissue level.

Senator **Hawkins**. All right. You stated earlier that the longer you studied the rat, the more correct the study would be?

Dr. **Friess**. Yes. One would want a 2-year study. In fact, we have been screaming since about 1981, that what we need for the risk-assessment process is a very low-dose level chronic experiment in the rat and the mouse, doses on the order of a part per million and lower in the food or in the water being taken in repeatedly by the rat or mouse model to give the kind of dose response data that we really need for projection to human populations eating traces in food or drinking traces in water.

Senator **Hawkins**. How would you know if EDB was the cause of workers getting cancer from such studies; how would you know?

Dr. **Friess**. This is a difficult process in epidemiology. You attempt to sort out the effect of the chemical from all other confounding factors, such as smoking and trips by airplanes with cosmic radiation, to sort the appearance of an effect against each possible contributing factor and you look for a clear, statistical association between the effect called cancer and what you are trying to measure with the confounding influences factored out mathematically.

Senator **Hawkins**. Is there a foolproof way to separate out environmental and dietary and hereditary factors in the risks of cancer?

Dr. **Friess**. The key word is "foolproof"; no. One only hopes to get a strong association first between the factor you are looking at and the dosing with the chemical, that is, it has to be clear first and then you factor away the confounding influences on that clear relationship.

Senator **Hawkins**. Well, if you can't do so, doesn't it make small population studies on human beings, as you put it, just exactly as the animal studies that you have described?

Dr. **Friess**. Absolutely, as I noted. Those studies have flaws when you only have several hundred workers in a population being exposed, but the proof of the pudding is that that's the target we are worried about and we can't duck away from those studies, even though the populations are small. There are much bigger populations that should be studied.

One hates to think about them, but knowing that EDB is ubiquitous throughout our civilization via our cars and gasoline, one would find interesting a study with huge populations of folks exposed to EDB via leaded gasoline for example; we don't have such a study; we work with what is available and has been published.

Senator **Hawkins**. In your opinion, would EDB in smog have an effect where they have a lot of automobiles?

Dr. **Friess**. It probably is in smog for two reasons; one, the vapors from gasoline stations and, two, the vapors spewing out from unburned gasoline from the older cars which use leaded gasoline.

I'm not certain, however, whether I would worry about that as much as I would worry about the spewing out of benzine from cars using unleaded gasoline.

Senator **Hawkins**. I guess we're going back to the bicycle.

Dr. **Friess**. If you can stay off of the road.

Senator **Hawkins**. We have a witness that is coming up here that I am sure you are aware of that stated in open court he thought that you might be the very best we had in this type of business.

Dr. **Friess**. I'm sorry there has been such a adverse viewpoint.

As far as I am concerned, my training, qualifications, and experience are such as to render my testimony at least comprehensive and sincere.

Senator **Hawkins**. We appreciate your coming here and sharing with us your experiences and your expertise.

I am sure the Senators will thank you personally for adding to this record, which is going to be of great interest to the entire Senate when we return tomorrow. Thank you.

The first witness on this panel will be Commissioner Doyle Conner, who is the commissioner of agriculture and consumer affairs for the State of Florida. We welcome you.

## STATEMENT OF DOYLE CONNER, COMMISSIONER OF AGRICULTURE AND CONSUMER SERVICES, STATE OF FLORIDA

Mr. **Conner**. Thank you, Senator. My name is Doyle Conner, commissioner of agriculture, Tallahassee, Fla. May I thank you for coming to Orlando, coming back to Florida to inquire about the subject under discussion here today.

I have submitted for the record a copy of my formal remarks and I think you have a sufficient number of those copies. I will summarize them and then yield to any questions you may have which will probably expedite things a bit.[1]

Florida's concern for EDB was triggered by the EPA inquiry into the California water situation back in, I believe, late June, where they discovered that certain wells were contaminated with the pesticide in the State of California from purposes similar to applications in the State of Florida. Having that knowledge in our department, we dispatched some of our inspectors to the most likely areas to discover if water contamination indeed did exist in our State. We drew the samples, ran the analyses in our laboratories, and found that we did indeed have some contamination. We don't have jurisdiction over water matters and we promptly turned this information over to HRS. HRS and DER have statutory responsibilities for water quality in our State.

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[1] See p. 116 for the prepared statement of Mr. Conner.

Ethylene dibromide has traditionally been used on citrus as a soil fumigant and you know the story there because it has been banned now for that purpose. After we found out that it had invaded our water supply in Florida, we immediately banned its use within the department of agriculture as a soil fumigant. In not too many days or weeks later, EPA did likewise. It was used extensively on golf courses, so some of our municipal water supplies have become contaminated from golf course use, some of it very close to your home. So I presume you are pretty acquainted with that.

The State officials set a standard for EDB in water at one-tenth of 1 part per billion. We have, as I said, an interest, but no responsibility in water. So the extent of our concern is cooperation with our sister agencies to try to provide as much information as possible.

We do and have had, I presume, for more than 50 years—I'm not old enough to really know—but for many years, probably around 50 years, we have had jurisdiction over food contamination in our State. Pesticide residues, and the regulations thereof, we have had that responsibility and have been conducting a program since about 1960.

In testifying before the legislative committees concerning the water quality, the question was asked about food. At that time, I reported that we had tested a number of products, such as beef, pork, poultry, eggs, dairy products, cereals, baby foods of all sorts, and a number of grains. All of those samples were negative, except two of the grain-based products had very slight traces of EDB—less than 1 part per billion.

At that time, we checked back on the trace situation because that did alert us to the fact that there could be a problem. We started our sampling program and did discover that we had varying levels of EDB in mostly grain-based products. The initial samples ran from the detectable amount, or thereabout, of 1 part per billion to less than a hundred parts per billion. Knowing that we had a problem, we immediately contacted the Food and Drug Administration. Even though EPA sets most of the standards in this area, Food and Drug is the enforcement agency, by and large, which we have worked with for many years—going back prior to EPA—on joint projects and laboratory contracts and grants and things of that sort, where we cooperate on Federal/State projects in the area of food. FDA responded and, I think, probably sent a copy to EPA. I don't know whether I sent a copy or my originals to EPA or not. FDA did inform us that they did not have national standards on a threshold for contamination of food products by or with EDB. Not having any national standards to go by and now having taken and analyzed more samples, these samples were ranging, at that time, from detectable amounts up to 755 parts per billion.

Now, bear in mind, we are not anything more than an enforcement agency. I did not have the capabilities and still don't have it, and it would be a duplication of effort, if we developed the capability in the department of agriculture and consumer services to determine at what point a product may become injurious to public health.

We did the next most logical thing. When we found out that there were no national standards, we inquired of our State health officer, Dr. Stephen King, gave him the results of our tests, both before and after cooking, and his people spent extensive time laboring with the problem that is before us today.

We asked him for a recommendation as to a threshold and safe standard. Since we did have contamination in water and now that we know we have contamination in food, we asked him to give us a recommendation on the standard. That recommendation was and is 1 part per billion on food products. We have followed that recommendation in making stop sales of products having in excess of that amount. At that time, or even before that time, if I recall correctly, we called on the national authorities to give us some standards. I think my reputation is pretty well known in the enforcement world. We are one of the States, one of many States that relies on national standards. In fact, our National Organization of State Departments of Agriculture firmly believes in national standards. I cannot think of any instance where we are not enforcing national standards where they are available. We have liaison task forces in our national organization which meets on a regularly scheduled basis with the Federal enforcement agencies. There is an EPA task force, NASDA/EPA. There is a NASDA/FDA task force. These enforcement agencies work very closely together.

In most instances, there are national standards available for us to adopt. In this instance, there is not one. As quickly as possible, there should be one. It's my understanding that the EPA, working with the USDA and the Food and Drug Administration, is diligently seeking to produce the national standards. This we highly recommend.

I have said before, and I'll say to your committee here today, the day they are made available to us, we will adopt them. Until then, we have a problem in Florida—a problem of contaminated water, which is being worked on and a problem of contaminated food. I don't know what this means to the public health of our citizens. There are people better qualified than myself to make that determination. But as a regulatory agency with a capability we think we have in food regulatory work, we think we have the capability equal to any State in the Nation and with our long experience in food regulatory work, I doubt very seriously if there are any better laboratories or any better trained technicians at the State level in particular. We think that we would be, by and large, on par with most Federal agencies as far as our performance is concerned.

Madam Chairman, we are continuing to conduct cookoff experiments. We have an intensive program. I think the EPA told us that they had received more information from Florida than any other State. Because we have been in this business a long time, we do have considerable data in this area and we have shared all of this data with the Federal agencies from the very beginning. We will continue to do that and cooperate in every respect hoping that soon there would be some national standards in this area.

I may point out that we are not finding 100 percent of the grain products to be contaminated—far less than 100 percent. Less than a third of those that we analyzed, or around a third of them, are contaminated. We are not removing total products from the marketplace, which might have been the impression that was left. Products that are not found to be contaminated may continue to be offered for sale in the State of Florida.

I will be happy to yield to any questions you may have.

Senator HAWKINS. Can you tell me how many samples of food products you tested so far?

Mr. CONNER. Well, we have tested about 273 samples totally, and we have issued—of course, you have lot numbers existing in many areas, many outlets, so we probably have several hundred or do have several hundred stop sales in effect.

Senator HAWKINS. Is that broadly representative or would you trace a lot of it to just one manufacturer?

Mr. CONNER. Oh, it's generally grain-based products. To begin with, mostly corn-based products, because we had not done extensive testing in other areas. But more recently, we have done more testing and cooking in other areas of food products.

Senator HAWKINS. How did the oatmeal turn out?

Mr. CONNER. Well, I don't specifically remember anything about the oatmeal.

Senator HAWKINS. I eat it every morning for breakfast.

Mr. CONNER. I need to know how long you need to cook it.

Senator HAWKINS. Did you test grits?

Mr. CONNER. We have tested, as I said, extensively the corn-based products, and since then, we have tested the others, the cake mixes and the cookie mixes, and we have also cooked those off. Additional data will be available soon on a more elaborate cookoff.

Senator HAWKINS. You are continuing to test?

Mr. CONNER. And experiment. We are doing extensive cooking now.

Senator HAWKINS. Are you shipping any EDB-contained product back to the manufacturers or are they being destroyed? What is happening to these that have been swiped off the shelves?

Mr. CONNER. We issued stop sales and then it's up to the manufacturer to—they just can't be offered for sale in Florida. I can't—maybe some of our inspectors could tell you specifically what happens to it—but the citation is issued and it can't be sold in Florida. The products would either go back to the distributor or they can do whatever they wish, but not sell the products in Florida.

Senator HAWKINS. Have your personal habits changed because of this recall order?

Mr. CONNER. No. As I said, I eat grits, wheat, corn, and other grain-based products. But I also said I don't have the capability of determining what is good for my health from that respect. I would have to rely on people who are authorities in this area and we are not trying to develop that capability in the Department of Agriculture and Consumer Services.

I think you have heard sufficient testimony here today that it's a responsibility of the Federal Government, because it requires so much elaborate research and so much data and I don't think any of the States want to undertake this responsibility as far as risk/benefits and all of these things are concerned.

Senator HAWKINS. Does the water table being cut close to the surface in Florida make a difference in your opinion?

Mr. CONNER. We feel that Florida is unique in our water supply and our naturally stored waters in our aquifers in Florida. A lot of them are shallow. We do have a different soil type, and the legislature in their water quality act—even though I have said we don't want to duplicate the work of Federal agencies—is asking us in the Department to make some evaluations as to how certain chemicals may react under Florida conditions. But that pertains to Florida soil, Florida environment, and our peculiar water storage, natural storage areas, so we will be doing some of that. We are proud of attempting not to duplicate the extensive work performed by the Federal agencies and seeking to have this information made available to the States.

Senator HAWKINS. If California had not requested the information from the EPA, do you feel that this would have been brought to light by the EPA?

Mr. CONNER. Well, I can tell you that we would have not because there are people who can more appropriately answer this question. But, if we had not seen the California situation and if we had not seen or had an experience in agriculture in Florida, we would not have thought of going to look if the condition existed. But knowing what we do, then we felt the responsibility to go look because there was a possibility that the same situation could exist in Florida. We knew about Hawaii and I had talked with the health officer there. We knew about California, and following that is when we tested our water here.

But I can tell you that we would not have gone and performed the tests, that are not within our jurisdiction, had we not feared there might be a problem here. We would have had no reason to do anything about it.

Senator HAWKINS. Whose responsibility is it to make sure that the water is safe in Florida?

Mr. CONNER. Well, it's HRS and DER, but our laboratories cooperated. If we discovered something in our laboratory that they needed to know, we immediately send it over to them, if they have jurisdiction over the area. If they found something, for instance, in food that we needed to know, they would immediately send it to us.

Senator HAWKINS. We appreciate your being so vigilant on this.

It seems to me there must be some standard, Federal or State, which requires periodical testing of the water supply.

Mr. CONNER. Well, now they do have—we are dealing with a very sophisticated test and I think they have hundreds of them now that the DER is conducting. But putting your finger on a problem that might exist is difficult. They can testify as to how many hundreds of tests they run. So this just happened to be something that was discovered. We knew there was a possibility of a problem and naturally, we would react on a situation of that sort.

Senator HAWKINS. Whose fault is it that over 500 wells are tainted—is that because the product was licensed incorrectly by EPA?

Mr. CONNER. Oh, I don't think so. There have been many hours spent trying to find out who's at fault.

The conclusion has been that we are discovering things that we didn't anticipate. I know we went through some criticism initially, that maybe we had not followed instructions, on the buffer zones. That was investigated extensively and found not to be the case. Of course, if someone is deliberately doing something improperly, I think we need to do something.

The question is now that we know we have a problem, what are we going to do about it? And I think most regulatory agencies have reached that conclusion—rather than trying to blame somebody—for something that may have existed over a period of 20 or 25 years. Only in 1983 did we discover that there was a problem with EDB in the ground water in the United States. This is with all the States looking at it and this is with all of the Federal agencies looking at the situation and a problem was discovered in June. There has been a timely reaction, particularly in Florida, to that discovery.

Senator HAWKINS. I appreciate so much your concern, Commissioner, and we thank you for coming here today. And we are developing a record, as you know, for the U.S. Senate Agriculture Committee to review. I am also on the Labor and Human Services Committee and that includes health, and if there are any answers for any other committees, we will call this record to that committee's attention.

Also, as you know, and as I have discussed, this is a national priority right now because the people are confused. It looks like from the testimony given earlier this morning, that EDB will be out of the food chain, and this is a short-term problem, but could bring long-term confusion unless we hurry and get the Federal Government to make a ruling.

Mr. Johnson testified before you came, that in the near future, EPA will be setting a tolerance. We are all looking forward to that time.

I appreciate your staying in touch with us.

Mr. CONNER. Well, let me assure your office and Mr. Johnson's and other Federal agencies that we will lend our full cooperation in attempting to supply any information we may have. We have done this and we will continue to assist them in their exploratory work.

I don't envy their position. But I repeat, we need uniform standards in the United States. Florida will follow those standards. Short of national standards, 50 States will find it necessary to embark on their own, and I feel that each of those 50 States has no desire to do that, the same as Florida. We would welcome national standards today or tomorrow.

Senator HAWKINS. But do you think there will have to be a standard for a peninsula like we have rather than like a landlocked State, in your opinion?

Mr. CONNER. Probably not. If we discovered an unusual situation based on our evaluation, then we will give this information to the Federal agencies and ask them to take it into consideration. But by and large, we can operate with Federal standards unless we find that they, in fact, impact so differently on a particular geographical area, such as Florida—and I realize what you're saying, but the Sun Belt is not that different is what I am saying. There are other areas in the United States that would have the same problems that we have in Florida. Louisiana is low, flat, and wet. Probably the most significant difference would be the oil they have that we don't have. But a lot of other things would be very similar so the Sun Belt has a lot in common.

And when working with Temik, I'm not sure that Temik reacted on Long Island the same as in the State of Florida. We do have some responsibilities in those areas.

Senator HAWKINS. So your advice to us at the Federal level would be to tailor the prescription to the geographical area?

Mr. CONNER. Not necessarily, unless testimony warrants that. What I'm really saying is we have some responsibilities to give you that information at the Federal level. We are asking for national standards and I don't want to complicate it. I would say give us national standards, and if we have some problems peculiar to our areas, the respective States I'm sure would respond. But they would welcome national standards more than anything else.

Senator **Hawkins**. That's what I'm trying to get into the record. You may not be happy with the national standards; I don't know. I don't know that anybody knows exactly what the tolerance level should be set at, but certainly regional variations should be considered. It's not even being manufactured any longer so we know the risk is short term.

Mr. **Conner**. I would say, let's get a Federal guideline and if we need to deviate from it down the road based on additional information, so be it. But the thing we need today is some direction at the Federal level.

Senator **Hawkins**. I can't recall on Temik; was that a Federal recall or guideline? I know it was used, then stopped, then used again.

Mr. **Conner**. Well, Temik did have a label and it was federally approved. There was a modification made by the State of Florida, based on a year's study, that did deviate because of the soil conditions in Florida. It did deviate from the national label, but we have the national label to go by.

Senator **Hawkins**. If you can tell me and the people of Florida that we have learned something from this episode, what would you tell them today?

Mr. **Conner**. Well, the first thing I woud tell them is that we are becoming very sophisticated in our detection techniques and the consumers of this State and the scientists of this country are not dealing in parts per million. We are already in parts per billion and parts per trillion now. It is something new. It's a real challenge to the Federal people and, I guess, we're saying that it's their primary responsibility. It's a real challenge for them to come up with safe levels, since we have this sophisticated analytical equipment. It's going to be necessary because we can find the most minute quantities of things that we didn't know existed 20 years ago. Some we can do something about. But there are many others that are not man-caused. We will know more about what is in the environment 20 years from now than we do today, and God knows we know a lot today about the chemicals and the natural hazards that man is living with. So it goes back to the risk/benefit, which is going to have to be a work of reality, and I am glad I'm in enforcement.

Senator **Hawkins**. Thank you, Commissioner.

Mr. **Conner**. Thank you, Madam Chairman.

Senator **Hawkins**. Good morning, Mr. Rhodes.

## STATEMENT OF HOWARD RHODES, DIRECTOR OF FLORIDA TASK FORCE ON ETHYLENE DIBROMIDE, FLORIDA DEPARTMENT OF ENVIRONMENTAL REGULATION

Mr. **Rhodes**. Thank you, Senator, for the opportunity to make a presentation on ethylene dibromide. My comments will be basically directed to ethylene dibromide in water and not in food. Ethylene dibromide, otherwise known as EDB, was first found in the ground waters of Hawaii and California in early 1983. The information became known to the Florida Department of Agriculture and Consumer Services, who have used EDB for approximately 20 years in the citrus buffer zone strips of the ridge area of central Florida to control nematodes. Realizing that there was a possibility that these applications could be causing a similar problem in Florida, the Department of Agriculture and Consumer Services began a private well-testing program in late June and early July 1983, as Commissioner Conner previously stated. The test results of several wells confirmed these suspicions. Several of these wells tested were indeed contaminated with EDB in quantities of parts per billion.

The Department of Agriculture and Consumer Services immediately notified the Florida Departments of Health and Rehabilitative Services and Environmental Regulation. It was decided in the ensuing weeks that the department of health and rehabilitative services would run the analysis on future well samplings, and the department of agriculture and consumer services would continue to assist on analysis as necessary. The department of environmental regulation's and the U.S. Environmental Protection Agency's laboratory capacities were and continue to be totally depleted due to the need to run analysis on toxic waste samples and superfund sites. In other words, we didn't have capability to run additional samples. The decision to have HRS provide major laboratory analysis support proved wise in the following months, but also showed the dismal lack of toxic laboratory capacity at local, State, and national levels. The HRS laboratory can only perform 200 to 250 samples per week for this single constituent, and the private wells needing analysis are in the thousands. Community water supplies number in the thousands. In the State of Florida alone, there are 500,000 to 700,000 private wells, and there is little capacity to test for large numbers of organic toxic chemical contamination.

The State agencies also needed to know as much about EDB as possible. Information was compiled. EDB had been described as a carcinogen in 1974 by the National Cancer Institute. The EPA had published some proposed restrictions on EDB in 1980, but soil fumigation was not included. Ground water studies were to be done first. Significant work had been done at the EPA up to 1980, but there seemed to have been little followup until 1983. Information on EDB was not easily obtained from the EPA because of the limits imposed on the EPA toxicological data received as a part of the registration process by the Federal Insecticide, Fungicide, and Rodenticide Act.

There was no standard for EDB in drinking water. The compound was found to be a strong carcinogen, mutagen, teratogen and was highly toxic. It was also discovered to be an unrestricted pesticide, meaning it could be used by anyone who wanted to, could use it. Except for the detailed records kept by the Department of Agriculture, no one knew how much, where or when EDB had been applied. HRS was able to establish that drinking two liters of water containing 0.1 per billion EDB a day for a lifetime would theoretically result in approximately 14 or 15 extra cancers per 100,000 population. Also, there was no demonstrated method of removing EDB from drinking water. The half-life in ground water was not known. Clearly, a problem was in the making, and few tools were available to deal with this problem.

More wells were tested, and each new batch revealed more contaminated wells. The news media began to carry daily stories on the contamination. More assistance to the affected well owners needed to be provided.

By the end of August, several community water supplies had been found contaminated. And in early September, Governor Graham, Commissioner Doyle Conner, Representative Sidney Martin and several State agency heads met to determine courses of action. They decided to acquaint a task force composed of four State agencies, and chaired by the DER, to oversee State agency actions as they related to the EDB contamination in drinking water.

The task force had several short- and long-term goals. Shorter term goals included providing water to citizens with contaminated wells, providing toll-free information hotlines, preparation of brochures and newsletters for persons with contaminated wells and just reliable information to concerned citizens. Longer term goals include determining the cleanup remedial action phase.

The task force found it useful to split the various tasks. Drinking water was sampled by local county health agencies and the department of agriculture and consumer services personnel; they were to be tested by the HRS laboratories; bottles and bottled water paid for by the DER and distribution points established by the DER; initial deliveries were made by local county health departments; and delivered to aged or infirmed provided by the department of community affairs and the Department of Agriculture.

I would like to carry that a step further, if I might. In any case where anyone was found that could not go and obtain water at a main water distribution point, water was to be provided to them and it was carried to them for that purpose.

HRS and the DER primarily provided brochures and newsletters to the public. The department of community affairs provided 24-hour a day telephone answering service, and HRS answered most questions related to EDB asked by the general public. This division of labor has generally been effective.

In mid-September, Commissioner Conner suspended the use of EDB for soil fumigation. Later, the EPA suspended the sale of EDB for soil fumigation, but its use has not been cancelled. With challenges, this may take a couple of years. Commissioner Conner subsequently banned its use as a soil fumigant because of the ground water problems. Thus, the material may be used elsewhere; but in Florida, it may not. This use restriction is clearly justified, and a method of indemnification and cleanup is clearly warranted before the product is cancelled. Provisions of FIFRA, as we understand them, do not provide indemnification until the product's use is cancelled. The unused material must be disposed of as soon as practicable, and not be allowed to be used or to corrode containers and leach to ground water.

EDB is used not only as a soil fumigant, but in grain preservation, as a lead scavenger in gasoline, in termite protection and other uses. In fact, 90 percent of its use is in leaded gasoline. Studies by the EPA's air program show that 99.6 percent of the material is destroyed in the internal combustion process. Underground storage tanks that leak to ground water though are a real threat, not only because of EDB, but also because of the gasoline. In addition to citrus soil fumigation, EDB has also been used in turf grasses for golf courses, on soybeans, peanuts, some tobacco, potatoes and other crops. The material is cheap and effective.

Since EDB is a volatile organic, it was believed that removal from water could be achieved by air stripping or activated carbon. No literature has been found to demonstrate this belief nor did the EPA have research to support this assumption. The manufacturers did not come forward with any information as Union Carbide had previously done with Temik. Discussion with the EPA revealed a contract with Environmental Science and Engineering of Gainesville, Fla. The EPA had awarded this contract to provide the necessary research to obtain this information for other organics. The EPA suggested that the necessary information could be obtained if the State split the costs, an EDB analysis could be performed economically. For the relatively economical sum of $15,000, the tests were performed. Results showed that EDB could effectively be removed from water by use of activated carbon, but could only partially be removed by air stripping. The State also purchased two commercial filters to test for EDB removal under field conditions. Results have been very helpful in determining design criteria.

The facts learned about EDB over the last few months tell an interesting story. It was thought that once EDB was found in the ground water, it would dissipate in a year or so. It has been demonstrated that EDB will contaminate ground water up to 15 years after application in soil similar to those in eastern Hillsborough County. EDB was found as deep as 800 feet in Polk County, demonstrating its contamination potential. As little as two or three gallons per acre can contaminate the aquifer in central and north Florida, but in Dade County, large usage has not resulted in ground water-well contamination that has been detected. Out of 2,800 tests, roughly 500 wells have been found with some level of EDB contamination. At least five community water systems have one or more wells contaminated with EDB.

In light of the above, the Governor and commissioner of agriculture and consumer services have asked that the testing be accelerated. This is being accomplished by the DER contracting with the State university system and providing funds to HRS laboratories to accelerate the analysis. Also, the DER is contracting with an outside firm to study the fate and direction of movement of EDB in ground water. These funds are being provided by the water quality assurance trust fund established by the 1983 Florida legislature in recognition of the significant ground water contamination problems yet to be discovered. To date, I have $12,000 but we now have $52,000 that has been spent for water supplies supplying clean water to its citizens. Over $1 million will be spent on preliminary studies, investigations and assistance to the public. Efforts to provide these services have been funded by the State.

Remedial action for well cleanup will likely be addressed the next session of the Florida legislature. The Governor has included the EDB task force's recommendations in the annual budget and will recommend that the State act to provide filters, connections to existing uncontaminated systems or new wells as necessary to those areas where the State has applied EDB. While the cost data cannot be refined until the exact treatment method is defined, and the total number of contaminated wells determined, an estimated cost of $4.5 to $5 million does not appear to be unreasonable. This cost, of course, could vary when refinements are made in the underlying assumptions and the estimates are made. That concludes my remarks. Any questions, Madam Chairman?

Senator HAWKINS. Thank you, Mr. Rhodes.

In September, as you know, the EPA issued an emergency suspension of EDB as a soil fumigant because of the concern for ground water contamination.

That action immediately halted the future use of EDB for this purpose, didn't it?

Mr. RHODES. It was our understanding when we were asking about this, that it forbid the sale of EDB, but did not restrict the use of the product that was already in stock. I would stand to be corrected if that is true.

Senator HAWKINS. So we can't use it in the soil, period; it's been banned?

Mr. RHODES. Yes.

Senator HAWKINS. Would you like to help us get rid of it altogether?

Mr. RHODES. It would be very useful if EDB can be used in other States. We know that it can't be used here in Florida at the present time because of Mr. Conner's directives.

Senator HAWKINS. Well, we will clarify that for you before you leave today.

Has it brought any hardships to the consumer?

Mr. RHODES. It's been a major inconvenience to a number of private home well owners who have had to go to other distribution points to obtain water. I think that has been the major inconvenience, that they have to close down the well that is contaminated and find other sources of water.

Senator HAWKINS. Would you say that there are at least 500,000 private wells?

Mr. RHODES. At least that number.

Senator HAWKINS. How many do you think have contacted you or the local authorities?

Mr. RHODES. Oh, about doing additional tests?

Senator HAWKINS. Yes.

Mr. RHODES. No, I don't have a figure on that.

Senator HAWKINS. How many have already contacted you and how many have you tested?

Mr. RHODES. We have the department of health and rehabilitative services which has tested 2,800 to 2,900 wells at the present time and we are continuing at the rate of about 200 or 300 a week.

Senator HAWKINS. And did I understand you to say that the local authorities are also testing private wells?

Mr. RHODES. No. The analysis is strictly being done in Jacksonville laboratories at the department of health and rehabilitative services.

Senator HAWKINS. So that total burden is on the DER or HRS?

Mr. RHODES. On HRS until we obtain some relief through the laboratories of the university's system.

Senator HAWKINS. How long do you think that will be?

Mr. **Rhodes** The contracts were signed last week. It will probably start next week when they start decreasing some of the capabilities. We anticipate that we probably will double our capacity, I believe, to run laboratory analyses within about 2 weeks.

Senator **Hawkins**. How long will it be before all the EDB-tainted wells are cleaned up?

Mr. **Rhodes**. That question is one basically of victim compensation. That has to be addressed both to the State and national levels, as we understand it. And the State, the legislature does not provide any resources during the last session for compensation. I believe the issue is also before the U.S. Congress, and to that extent, as I understand it, that bill has not been approved, either.

Senator **Hawkins**. How many people do you think were drinking from EDB-tainted wells that you have identified so far?

Mr. **Rhodes**. For private wells, the figure is roughly, I would say, about 500, and municipal supplies, I would imagine the figure is about 32,000 to 34,000. However, that 30,000 is one system, and that is the city of Sanford. It subsequently shut down each one of these wells and have replaced the water supply with EDB-free wells.

Senator **Hawkins**. Will you continue to test other wells?

Mr. **Rhodes**. We will anticipate as more wells are tested there would be additional findings of EDB contamination.

Senator **Hawkins**. Have you changed your eating habits and drinking habits, water drinking habits, since the discovery of EDB in our food and water?

Mr. **Rhodes**. Not at this time. I still eat pretty much as I had.

Senator **Hawkins**. Just describe to me the relationship between your agency for monitoring drinking water and the Federal Government's responsibility to monitor local or State water? How will you work with the other agencies in this State for testing water?

Mr. **Rhodes**. We have basically a division of the drinking water program between the Department of Health and Rehabilitative Services and our agency. They have primary responsibility for testing private wells and for doing analyses on the municipal supplies. However, the enforcement programs and design engineering and other factors enforcement fall under the department of environmental regulation and we have the responsibility for carrying out the Federal program in Florida.

Senator **Hawkins**. And with such a large amount of EDB placed in the soil for so many years in Florida and with the water table so close, it seems to me that the State officials would be watching constantly for the invasion of any type of toxic chemicals.

Is that an on-going test?

Mr. **Rhodes**. We are, I suppose, like everyone in the country; we spent most of the early seventies looking at surface waters. The issue of ground water contamination was one of priority and also one of detection. Until the midseventies, as I have heard discussed here today, the issue of being able to detect small quantities of toxic chemicals in the water just was nonexistent. That issue has now been resolved by a better instrumentation, and as a result of it, the State is moving more and more in an area of looking at ground water contamination through toxic chemicals, through better testing methods. However, we are finding that once we find a chemical, we have no basic standards for those chemicals at the State or national level, so that has begun to prove somewhat of a problem.

Senator **Hawkins**. What do you do when you find that? Do you have an 800 number that you call?

Mr. **Rhodes**. We try to find out all of the information that we can about the chemical, what toxicological data there is, see if there are any standards that had been set by EPA for drinking water; if not, then we essentially have to move to general health restrictions if we find chemicals in the water and we will be moving more in that direction in weeks and years ahead.

Senator **Hawkins**. How often do you test for well water; when it's requested or do you have an ongoing program or as technology gets better to screen for toxic chemicals?

Mr. **Rhodes**. Fundamentally, up until the last 2 or 3 years, there has not been a program anywhere in the country to test for toxins in drinking or ground water. I think it's been a general recognition that there is a real problem in this area and that there has been a greatly increased awareness at all levels; more needs to be done. And as a result of that, two or three things are happening: The States have just passed a water quality assurance act, which directed a lot of research into ground water monitoring. HRS has been concentrating a lot of their monitoring activities in these areas, but as I mentioned earlier, there is a drastic lack of resource capability and literally, it's difficult, but not impossible, to test all 500,000 or 600,000 wells in the State. I think we have to pinpoint specific areas where there are problems and test those types of wells.

Our monitoring program should begin to pick up and show us where the problems are so we can ask the health department to start to look into these areas for these specific chemicals.

Senator **Hawkins**. I know you are busy right now with EDB, but are you testing for other pesticides as well as EDB? While you're testing that water, are you testing other pesticides?

Mr. **Rhodes**. This is what we would like to do. As I mentioned in the capability, about 200 to 250 samples per week per constituent. When the university system laboratories come on, we are commencing with a program doing some scan on representative samples from a given area by looking at the types of pesticides that are used in that area and then testing for those in some representative samples.

Senator **Hawkins**. Since the EPA banned the use of EDB in September, how long do you expect the EDB will stay in the food chain; do you have an opinion?

Mr. **Rhodes**. I can only speculate, Senator. At the present time, my only real clue is in Hillsborough County where we know that EDB was applied in the buffer zone in about 1967 or 1968 and that was the last known application. Subsequently, wells that are fairly close or adjacent to that site have been found to be contaminated with elevated levels of EDB.

Senator **Hawkins**. How high?

Mr. **Rhodes**. I can't give you an answer. I can follow that up, if you would like, but I believe it was in the range of about 1 or 2 parts per billion.

Senator **Hawkins**. 1 or 2 parts per billion in Hillsborough County?

Mr. **Rhodes**. Right.

Senator HAWKINS. What is a safe level; 1 part per billion?

Mr. RHODES. Dr. King has earlier given us a figure that one-tenth of a part per billion should be the level which the EDB standard should be established or at least for an interim solution.

Senator HAWKINS. For drinking water?

Mr. RHODES. So these levels would be between 10 and 20 times the level that he had suggested.

Senator HAWKINS. Could you give us any recommendations that the Senate Agriculture Committee or anything that needs to be done in your opinion with this experience that we have had in Florida?

Mr. RHODES. Perhaps I can suggest two or three that would be particularly useful, would be to have an acceleration of EPA's program initiative in ground water activity so that we could begin to have a national standard for most of our toxic chemicals. It makes it extremely difficult, as Commissioner Conner indicated, for us to have to contemplate having 50 standards around the States, and we would very much like to have a national standard for chemicals like EDB and other toxics like trichlorethylene in drinking water.

We then could use an enforcement tool to take that through the legal process to obtain compliance.

Senator HAWKINS. Thank you for your interest in these areas and following up on the problems that we have statewide. In your opinion, is drinking EDB water as dangerous to your health as many other chemicals we take into the body?

Mr. RHODES. I would have to just purely offer this as my own opinion and not representing my agency.

I would think that cigarette smoking is probably a lot more dangerous on a statistical-risk basis.

Senator HAWKINS. Thank you.

Mr. RHODES. Thank you very much for the opportunity.

Senator HAWKINS. I appreciate you being on the task force.

This is Dr. Stephen H. King, M.D., State public health officer for the Department of Health and Human Services.

## STATEMENT OF STEPHEN H. KING, M.D., STATE PUBLIC HEALTH OFFICER, FLORIDA DEPARTMENT OF HEALTH AND REHABILITATIVE SERVICES

Dr. KING. Good morning. Madam Chairman, I believe you have my prepared comments, and what I will do is spend a very few minutes summarizing those, but most of the comments which I made, have been made already, I think.[1]

When you sent the letter asking me to come to this hearing, you asked a series of three questions. What I will try to do is to speak to those three questions in a basic sense.

You did ask: What is the level of EDB the people of Florida and elsewhere in the United States are exposed to?

It's in our feeling that Florida residents are exposed to this chemical from two main sources. That is from the drinking water and from the grain products in food. Of course, the individual risk depends on the length of exposure for that individual and the degree of contamination to which that individual is exposed from both of those sources. So in dealing with the situation, you both have the problem of the individual as well as population-based issues. It would be extremely difficult, although we are going to make an effort to do so, to deal with the individual risk, so that for populations that we are aware of that have been exposed to EDB over a period of time, we can do a number of studies. Hopefully we can do some of the definitive epidemiologic studies, which were previously alluded to, and which desperately need to be done on a scientifically valid basis.

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[1] See p. 119 for the prepared statement of Dr. King.

As you have heard, there have been approximately 3,000 well samples, and a significant number of those are positive. That has been one source of exposure for a fairly large percent of the State.

To date, we have only dealt with those areas which were in the ridge, the hills down through the middle of the State, where there has been the use of ethylene dibromide in citrus barrier zones and also in the other areas of the State where ethylene dibromide has been used in such places as soybeans and peanuts. Those are the areas where we have concentrated our efforts right now.

As Mr. Rhodes mentioned, we are just before expanding that effort by several fold and should have several thousands, 10 or greater thousands, samples for you by the summer.

At this point in time, we have done 3,000 wells and that really does represent a large number. The technology involved in doing this task is quite complex and I think most of the folks working in the laboratories for this particular substance realize that even the ability to do a couple hundred a week has represented for us in public health and the department of health and rehabilitative service working overtime, several shifts a day. People have really been working quite hard on that. It's a big issue for us.

You have already heard that the issue began here after the prior discoveries in Hawaii and California. The efforts that we have had in public health has been directed up until very recently at individuals who are serviced by water supplies who have a 0.1 part per billion or greater in their supplies.

The majority of the positive samples have been in private wells. We have personally communicated with all of those individuals about the nature of the risk and we have advised them to seek alternative supplies of water for cooking purposes and drinking purposes.

I think this has already been mentioned, but this is a preliminary level. The recommendations are on an informal basis were given to us by our sister agencies at both State and Federal level suggested, that even a lower level might be warranted than the 0.1 parts per billion. Most risk determinations are made by determining what point a certain level of exposure in a population of people who are exposed for a lifetime will suffer greater than an increased incidence of 1 per 100,000 malignancies. The usual cutoff is between 1 million, 1 in 1 million, and 1 in 100,000. That has been traditional; that has been set over the years and has been used as a benchmark against which we look into the actual risk if we can in fact accurately determine the average dose of the individual person. It's much easier for water than it is for food, by the way.

Everybody does consume approximately 2 liters of water a day, and if we know that their own source of drinking water is their own private well, for instance, or whatever water supply they might have, we can accurately determine what their dose is going to be. The problem, of course, is much different with food, because all of us consume grain products in far different ways than others even in our own family. I think the original concern on the grain that came out of the EPA's documents that were provided earlier in the fall did reflect the fact that grain products do represent a fairly large percentage of the average American's diet.

How dangerous is this level of exposure?

As a State health officer, I have relied almost exclusively on the EPA's document, Position Document 4, which was published on September 27, 1983, and came out as part of the actions they took in September when they dealt with the issue of EDB that was presently being used as a soil fumigant.

And you asked a question in previous testimony as to what that actually did. They recommended that three things happen: They recommended that there be an emergency cessation of the sale of EDB for the purposes of soil fumigation. Mr. Rhodes was correct in saying that there—the difference between the action that Florida took and that EPA took, Florida's actions came several days or weeks before the EPA's, was that in Florida, we also removed from the shelf the EDB that was there. The other two actions that were taken by the EPA were that they would cease use as a fumigant for grains and storage and grain and milling equipment during the process of milling.

That was not an emergency ban and, therefore, was subject to due process and has been appealed, and as the Federal Register so states in its October 11 comments on the emergency ban of EDB as a soil fumigant, since they did have data at hand at that point that found in fact that EDB was leaching into ground water, a fact that was not as greatly appreciated prior to this last summer, had been they felt they should take the emergency action for soil fumigation.

They also mentioned in that Federal Register that when they don't take emergency action and since they had recommended that the use of EDB for fumigation and food, and fumigation and citrus be stopped, the legal process and appeals could take 3 to 4 years or longer, and this was a factor, by the way, in the decision here in Florida to go ahead and take action when it was discovered in food. All of the information available in this document, much of it was available as early as 1974 and 1975, which also represents, as I understand it, the final position document of the EPA regarding EDB, and it states that this chemical is highly carinogenic, mutagenic, and produces adverse reproductive effects. That information was available to the general public, to the industry community and to the scientific community for comment as early as Position Document No. 1 and as early as Position Document No. 2/3, which was available in 1980.

Senator HAWKINS. Excuse me. Which established that 35 parts per billion?

Dr. KING. 35?

Senator HAWKINS. Yes.

Dr. KING. The Position Document No. 2/3 in 1980 suggested that the worst possible case for exposure to humans in grains would be 35 parts per billion. They changed their recommendation between 2/3 to Position Document No. 4 based on a couple of facts: One, they changed the methodology of determining the degree of risk between these 2 years. There were two other things that occurred. There was further substantiation of its carcinogenesis by other routes of exposure and they also found that in an article which is mentioned in Position Document No. 4, but even after cooking in a cross-country sample of grain products available to our schoolchildren for the school lunch program, that ethylene dibromide remained as high as 260-plus parts per billion in baked biscuits. Between those two, PD 2/3 and 4, there was an increased concern on the part of the people putting out that document, EPA, of the degree of risk of EDB in our food.

As I said, as a State health officer, my information and my basic recommendation to Commissioner Conner in the earlier part of December was based on the information available in that document. It was a recommendation and it was clearly at interim level. It was not based on any particular relative risk, but on the fact that that level was the level that the laboratory could reliably determine the presence of ethylene dibromide and it was subject to a recommended level by the EPA, which, though, I think the State of Florida should reserve the opportunity to look at that level, and in the scientific basis for reaching that level, I believe the State would be in a position to happily welcome that level, were it offered.

One of the things I think is important that has already been mentioned is the fact that the period of time that EDB will be present in food depends entirely upon its absolute restrictions as a use—for use as a fumigant in grain.

I think it has been mentioned before, I think, that once that determination is made, and also this has been said in earlier testimony, I think, it is also possible to remove by a variety of means this grain which is presently contaminated from our diet.

And that leads, I think, fairly directly to your last question as to what steps should be taken to lower exposure to EDB?

The water testing program poses us a dilemma. We are presently dealing in those parts of the State where we know the potential for contamination to be greatest. I think that, as we finish off that area of the State, I suspect—I certainly hope that a number of positive samples that we continue to retrieve from a wider basis sample, will prove to be negative. Nevertheless, we are faced with the dilemma for the individual homeowner who has a private well and whose water is contaminated at perhaps a significant level at the present time and who not only has the personal inconvenience of not being able to drink the water and cook with it, but also who finds that there might have been even some effect on the property values of the property that they own. I think that that part of the problem—and it's not strictly a public health problem—is one I have heard from home and landowners and private well owners frequently.

I think the exemption from registration of ethlylene dibromide for grain, mill, and soil fumigation in the fifties was based on the assumption that EDB would quickly degrade and evaporate, leaving no persisting soil or grain residue. This is not proven to be true, although that exemption continues in force.

I urge that that exemption be addressed immediately. That is one thing that would be very practical and an immediate thing to deal effectively with the problem of the utilization of EDB in mills and in grain elevators and other storage areas and that is the removal of the exemption for its use for those purposes.

Grain and water—and it has already been banned as a soil fumigant, so all we've got left to deal with the problem of what is down there, and we will know better by next summer when we go back to the first set of wells that were positive and look at what those levels are and we can begin to get some idea of degradation. Also, we will have to take into consideration when we do that, however, is the fact that this water is also flowing underneath our soil and we have to take that into consideration as well. But, we will be able to tell you better next summer of what the fate is in soil.

Grain and water are among our Nation's—and indeed the world's—most valuable resources. EPA Position Paper No. 4 definitively states the potential danger of these resources to man. Elimination of this threat is clearly a national issue requiring careful analysis. Acceptable residues, if any, in food products must be prudently set by the EPA as quickly as possible. In the absence of such standard-setting, however, we can do no less as State officials than exert our best efforts to protect the health of our citizens.

I would like to close by asking that those who are in a position to shape and implement public policy recognize that one of their first responsibilities is to protect the public's health. St. Thomas Aquinas, I believe, said something to the effect that real generosity toward the future consists of giving all to what is present. It is in that spirit that I urge the EPA to set standards for human exposure to EDB immediately.

Madam Chairman, I hope you will join me in this request. Thank you.

Senator HAWKINS. Were you here for the testimony this morning?

Dr. KING. Part of it. I believe it was the Department of Agriculture's statement.

Senator HAWKINS. Mr. Johnson will give you a copy of his testimony. They are moving rapidly.

When you, as a scientist, look at the total burden of EDB, do you feel that Florida's standards should be less than the national standards in light of our already having the water contaminated?

Dr. KING. I think it's a very cogent question; it's a very difficult one to answer. I have been thinking about that and there are a number of ways they can address that.

What I guess—I suppose set a separate standard from the rest of the country. That would suppose that we had the technological capacity to duplicate everything that the EPA in its contracting can do with agencies and data. We can't do that. We really do have to rely for an awful lot of our technical data on what they provide and what the manufacturers provide to the EPA and, of course, in the registration of their pesticide.

What we can do, and a role I think belongs in the realm of public health, is to deal with the personal contact with those individuals whom we have identified as being at risk or potentially at risk. And through the media, through public information, through what we have found to be very effective in our one-on-one experience with the folks with water, is to help them through a difficult time and advise them how they can change their food habits. I am sure that the State will continue to be testing that in its food so we know which foods are in fact with that EDB in them.

One of the big questions that seems to be needed is: OK; we know which ones are positive, have EDB in them. Which ones are negative? Which ones that we have sampled that we know are negative, and that's the best preponderance of what we have tested with that information. I think we can deal with the issue for individuals if, in fact, the level were to be higher than would be appropriate. We may have to deal with that.

Once we have identified that population base that is an additional risk because of water, I think we can probably deal with a level which otherwise might should be lower than the national level, but I think we can deal effectively with that and accept the national level as well.

Senator HAWKINS. Even if it's higher than the 1 part per billion?

Dr. KING. Right. Remember, the 1 part per billion was clearly an interim level. It was not intended to be a level below which human toxicity did not occur and above which human toxicity did occur. It was the ability of the laboratory to determine its presence.

The EPA in its documents have already determined that it was a toxic chemical and suggested that that exposure from grain alone was quite high, and on the basis largely off your water data, that the additional water burden was also excessive.

Now, I think if I accept that, that the decision that the EPA will have to make is not absolutely 100 percent, one which I, as a physician in public health, perhaps would ideally look for, but we live in a pragmatic world in which this is an industry which is important to us and to the rest of the world. And I hope that we can spend our energy and efforts towards a cleaning up of what we have and find alternatives which is to take pesticides out of grain. I think we can do that.

Senator HAWKINS. EDB has been found in food and ground water as testified here and stated.

For a residence in this "hill area", are you saying its the central portion of the State?

Dr. KING. Central ridge.

Senator HAWKINS. Which source of contamination, water or food, in your opinion, was a more dangerous source of EDB exposure?

Dr. KING. Potentially, we'd have to give you as an assumption, a certain level of water and a certain level in foods, and that's the answer to that question in a precise manner.

If you took the levels which tended to be the most common, when it was possible, which is around 1 or 2 parts per billion in water, and the levels which have been the most common when it's been found in foods, which are around five plus or minus two or three in food.

Senator HAWKINS. Is that uncooked or cooked?

Dr. KING. That is uncooked, that is if the person baked their own bread, for instance, and stayed at home, the risk would be approximately equal. If, however, their main carbohydrate source was grits cooked at boiling temperatures on top of a stove with a lid on the pan, the retention of the EDB could possibly be significantly higher, particularly if that individual also doesn't drink much water but consumed other liquids of another kind which would not have EDB in it, then the risk would be greater for the food and less for the water, so you would have to deal with each person individually before you can say that. I think both of the risks, when you look at them on a population base, are pretty close to equal. In this State, we are finding ethylene dibromide in the water.

Senator HAWKINS. Why haven't other States which tested for EDB-treated foods removed the food from the shelves?

Dr. KING. I think Florida found itself in a situation it was in the first week in December through a course of events which started late last spring. I think in any State—I am absolutely convinced of this—any State which found itself with a positive water supply, would have begun immediately to check for food as we did in the State of Florida. That was as natural as day follows night, particularly given the document provided by the EPA in September.

I was quite relieved the first 2 or 3 months when we did not find positive food supplies at all and I thought at the time how lucky we are. However, we did find them in December.

I believe that the majority of the State health officers in other parts of the country and the majority of the people in both the Health Service and EPA, who work on this technical basis, feel very strongly that, given the choice of whether to continue to allow sales to consumers of a product known to contain the substance, would elect not to do so if asked for their opinion.

Senator HAWKINS. Did Florida take the food products off the shelf before or after testing?

Dr. KING. No. They were sampled by the Department of Agriculture, as I understand it, and removed to the laboratory and tested when they were found to be positive and the determination was made that they would in fact stop sales. At that point, the Department of Agriculture took whatever procedures they take to deal with the retail merchants, who then are simply not allowed to sell it; they must remove it to other places in the store, and how they dispose of it or redistribute it at that point, I simply don't know. It was after the testing that the determination was made to stop sales.

Senator HAWKINS. Do you believe that the State over the past 10 years has taken adequate action to protect the drinking water from contamination? Could we do more?

Dr. KING. In looking back on hindsight, it gives us a great deal of advantage. I don't think people 10 years ago appreciated how delicate Florida's ecology is, how greatly we depend upon water, on that water that sits right underneath the surface of our soil. It affects virtually everything that we do in commerce, in our private lives, in our tourism, in the food that we eat, and I think that had we known 10 years ago what we know today, we perhaps would be feeling or would have done things differently. But we didn't do that.

And I'm sure that anybody in this room or anywhere across the country knew then what we know now, but we do know now, and I think we have begun and the legislature in this State has begun to support very significantly our efforts to clean up the water supply.

Senator HAWKINS. If the EPA set the standard at 100 parts per billion, would you accept it, if they justified it?

Dr. KING. That's like the one, if the frog had wings.

Senator HAWKINS. If they justified it.

Dr. KING. If they justified it——

Senator HAWKINS. If they scientifically justified it.

Dr. **King**. Well, if they scientifically justified it, then, sure. I think if the level were that high in some types of foods, they would have a problem justifying it. It depends upon its preparation and consumption, but, again, I am speculating at this point and that's a very dangerous thing to do I have found.

Senator **Hawkins**. We heard testimony this morning that EDB is not being made any more; they have stopped the manufacture of EDB. Were you here when they said that?

Dr. **King**. No, I didn't hear that. And it surprises me somewhat.

Senator **Hawkins**. As a grain fumigant.

Dr. **King**. It's being manufactured for grain?

Senator **Hawkins**. Yes.

Dr. **King**. I don't know that anybody can necessarily say it's not being used as a grain fumigant. The people in the industry who carried on a discussion with me of some depth over the last couple of months have said that their problem is not so much in the storage and the elevators in the big silos, but the problem is with the small farmer who must protect his grain to keep it in a salable condition in his little crib or elevator at his farm. And that it is in some of those instances the level used may be quite high and that is not something that the industry, itself, can regulate. They simply buy the grain from a number of small farmers, take it to the elevators, bought from the elevators, as I understand it, by the milling company, and then is sold as a finished product.

Now what happens at the farm site is not controlled as far as I can tell by anybody at this point because it is, in effect, excluded from registration control at that point at the present time and that's one of the reasons I said earlier I thought one of the most important things was to remove that exclusion.

Now, I do believe that the industry is acting very responsibly in that they said they have stopped using any supplies that they know of that has EDB in them when the grain is in their control.

Senator **Hawkins**. If they were to stop manufacturing it then, they would have to stop using it; wouldn't that follow?

Dr. **King**. Yes.

Senator **Hawkins**. Eventually, wouldn't it?

Dr. **King**. Yes. There are a number of uses that they still use a significant amount of it for gasoline.

Senator **Hawkins**. Do you have any fear about the leaking gasoline tank—storage tanks that we heard about today?

Dr. **King**. We have quite a problem with gasoline in water supply. As it—those old tanks, you know, the highways that are no longer used in Florida as they once were before the interstates were constructed began to leak and erode into our water supply. The major problem there is the gasoline, itself, and the many other chemicals that are in gasoline. As far as I know, we have not specifically documented a positive ethylene dibromide in a water supply due directly to leakage of gasoline. And as far as I know, all of the positives are due to our best judgment from leaching from use as a soil fumigant in agriculture.

Senator **Hawkins**. How about golf courses?

Dr. **King**. Yes.

Senator **Hawkins**. I believe that was alluded to by the State.

Dr. **King.** Yes.

Senator **Hawkins.** And the EPA?

Dr. **King.** Yes. You see, there was no control over its use as a soil fumigant. The assumption was made until very late in the seventies that EDB had its course of action because of a bromine molecule that broke away from the compound and it was that molecule which has the effect similar to the way we chlorinate or brominate our swimming pools, but that's not the case with ethylene dibromide; it stays stuck together and leaches as a parent compound staying together as a parent compound and that fact was not clearly understood until the late seventies and early eighties. That's why the never thought it would be a problem in grain, a problem in milling equipment or that it would be a problem in soil fumigation. And our information is really quite recent on that.

Senator **Hawkins.** The wells we talked about in Hillsborough County still have EDB in them after, what, 15 years?

Dr. **King.** Yes.

Senator **Hawkins.** Doesn't that make you concerned a little bit about there being a separate standard for Florida over a State that may not have it in their water supply?

Dr. **King.** I'm sorry?

Senator **Hawkins.** If the EDB stays in the water for 15 years?

Dr. **King.** Yes.

Senator **Hawkins.** Say another State has no EDB in their water system as we do, wouldn't the national standard be wrong then for—it would be wrong for one of the two States?

Dr. **King.** We have had a good deal of ongoing communications with the Environmental Protection Agency. I think that their actions were quite responsive in dealing with this problem of soil fumigation last summer and I have had no evidence to date to suggest that they wouldn't continue to be.

I do recognize that this is a major problem of social and political consequences as well as just the consequences about what I may be concerned. Again, however, without training, without guidance, with only information available to us that it's a dangerous chemical, those of us who I feel have some stewardship and responsibility for the public health and I think EPA and that group must always find, when there is any doubt, for the public's health.

Senator **Hawkins.** Have you changed your personal eating or drinking habits, water habits?

Dr. **King.** Well, first of all, a number of us in Tallahassee were concerned about water supply in and around Tallahassee and I'm quite confident it's been found to be negative. And I find personally that I consume very little grain products. And that's changed from my childhood; I recognize, but in looking at the 5-pound sack of wheat that has been in our bin in our kitchen—it's been there for quite some time it turns out, I mean, I think we moved with it the last time we moved. So I know that it's not at least one of the positives that Mr. Gardner in the agriculture laboratory found.

Senator **Hawkins.** I've been told that the laboratories throughout Florida now at least in central Florida can test children for EDB in urine.

Dr. **King**. That's news to me. As a matter of fact, one of the real problems is how to effectively measure a human body burden that is not only what they might have consumed that day, but also hopefully would represent reflection of what they had over time. This is a critical need. A number of us have been talking about exactly how we would check a human population; no one would be exposed, and try to differentiate out of those who had the biggest burden; that's going to be very tough within the limits of our technology, I'm sure, but it's really very tough. So what you say is news to me.

Senator **Hawkins**. That's true. Well, a pediatrician called me and said his laboratory can test for EDB and Temik in urine. However, the evidence we have gathered in the hearing today states that in 3 or 4 years we will be out of the chain.

How do you feel about the long-term exposure?

Dr. **King**. There is a log in the literature about the pathophysiology of malignant disease, its onset, its mechanisms of its onset, the kind of stimuli that leads to the recognition of malignant disease, and all of those hold two or three things in common, however. The event that occurs today, which ultimately and for whatever reason, leads to an expression of malignant disease in later time, is controlled by a host of variables, many of which we are beginning to know. Cancer research is quite good, as a matter of fact. I believe that some portion—I can't tell you how much—of the burden of malignant disease presently in this population, as was previously stated, I doubt it's anywhere near the malignancy caused by cigarette smoking is due to EBD, and to related halogen and hydrochloride which malignancies we see in our friends, neighbors and/or the rest of the population out there is specifically due to EDB, I don't know. But I do know that the vast majority of malignant diseases in our population in this country is due to environmentally caused events, and any opportunity that we do have to take control of it, EBD, I think that's a stewardship responsibility of the State and Federal Government. Smoking, I think it's fairly clear that the public out there knows the mistake they are making and they do have the choice.

Now, I'm not sure that if I had the authority to do so, whether I would change that. I don't think I would.

We make many choices and freedom is choice, when we know the risks that we have, but that's one of the nice things we have.

Senator **Hawkins**. You also have the freedom not to do detrimental things to your health.

Dr. **King**. Yes.

Senator **Hawkins**. There are those that are out there that don't believe any of the scientific jargon that you all talk about every day and they will die of something, so they might as well enjoy it.

To me, I think we should be cognizant of the warning signals and scientists have a stewardship that you talked about as I feel we all do, to alert those who can't take care of themselves to the potential dangers.

Can the people of Florida be assured that there won't be any other episodes involving chemicals in drinking water, because we are going to expand testing of ground water?

Dr. **King.** I think in future years ahead, it's going to be a lot better than it was in the past. There was an appreciation of the importance of this whole environmental issue on the part of the people who make policy, people in legislature and elsewhere in the State and local as well as Federal Governments around the country.

I'm absolutely convinced that the years ahead will show one of the greatest strides made in protecting the health of all of us. It's going to be an increasing understanding of how we deal effectively with this interaction with our environment. It's within that frame of reference that I think that we are going to succeed a great deal and I think the Government is going to have to help us do it.

Senator **Hawkins.** Thank you. I appreciate your testimony here.

Dr. Szabo, a physician and friend, who has been requested to give a statement for the record.

## STATEMENT OF JAMES IMRE SZABO, M.D., WINTER GARDEN, FLA.

Dr. **Szabo.** I have just a few words to say to try to clarify.[1]

I am Dr. Imre Szabo—I-m-r-e—Szabo, S-z-a-b-o.

EDB is not a new problem. It's always been with us. It's present in the atmosphere. It's been present ever since time began. It's present especially in high concentrations in the antarctic and in the very early spring and winter. It's nothing new.

And also a concentration of it depends partially on the amount of bromine in the area; seafood and salt water areas happen to have higher concentrations than would be other places.

Boiling water and cooking and things like that will partially destroy EDB, but a certain amount of it is given off in the steam, and if you breathe it by steam, you will get the EDB.

How much the EDB hurts us depends partially upon the mass of material we take in. If we only take in a few ounces of cereal that have the same amount of EDB in it as per mass compared to water when you take in 72 ounces of water, why the ratio would be proportionate to the amount that you took in as a mass. Therefore, don't worry about the oatmeal; worry about the water it's cooked in.

EDB lasts longer in cold, dark places, therefore, it lasts longer, for a longer time where it's cold and dark. You can destroy it the more oxygen that is exposed to it, the more heat that is exposed to it, the faster the degradation takes place.

There are certain organisms that possibly could be developed that would metabolize EDB. We have metabolized most of our carcinogenics by various micro-organisms.

EDB is fat soluble and will attach to the cell lipids, cell membranes, and it can also attach to the DNA and RNA causing chromosome changes which cause it to be mutagenic or carcinogenic.

In our laboratory, to test properly for EDB, we should start with young, female rats, who have never been impregnated, and should give them a certain level of EDB for at least a month before they become pregnant and then run tests on the rats periodically and note the amount of malformations that are formed by EDB in the newborn and also for shortened lifespan of the rats that have been exposed to EDB. When you are giving tests, otherwise, it's not very significant, but will not give you much of a very good answer, because you're using EDB by gavage, which is ridiculous. And 13 weeks is not long enough to use it. It has to be used during the rat's entire lifespan.

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[1] See p. 122 for the prepared statement of Dr. Szabo.

Now, the effects of EDB depends upon the metabolic rate of the animal and its lifespan. In a short lifespan organism, like the fruit fly Drosophila not only has a 24-hour lifespan which will be much more markedly affected than a long lifespan creature.

The rat is affected—will live 3 years and will be expected to die much more markedly affected than a man who is only exposed to it for 3 years. A human being that is, for round numbers, say, has a lifespan at 60—of course, it's more than that—but, if you expose a man to a span of 3 years, it's effect would only be 1/20th of that of exposing a rat to it for a lifespan of 3 years.

The human body has the capability of repairing the DNA and the damage done by EDB if it is not constantly reinforced. You automatically expell 50 percent of the intake within the first 24 hours and the second 24 hours, you will expell about half the rest of that, but there is a certain small amount that lingers for a long time. This is a problem. The more rapidly growing cells are the ones that are affected the most; therefore, when you have the young female rats that become pregnant, the embryo will be affected most and the effect on the embryo will not only be for this generation, but also for subsequent generations, whereas, the male's sperm cells are constantly being reproduced and most females have their ovum at the time of birth and, therefore, they will not give you a true accounting; you must produce a second generation of the rat to get an accurate account of the effects of EDB.

Any questions?

Senator **Hawkins**. You feel that tobacco smoking is harmful?

Dr. **Szabo**. I definitely do, yes.

Senator **Hawkins**. Is there scientific data?

Dr. **Szabo**. The scientific data has been—I've seen people die of tobacco in my practice all of the time. I think tobacco is much more harmful than EDB is.

Senator **Hawkins**. Thank you, Dr. Szabo, for caring enough to testify today. I know you have a very busy practice and I appreciate your attention to this problem.

I would like to state for the record this will remain open for 10 days. If any of the Senators who are members of this committee or any other Senator, for that matter, wish to make a statement then they may do so in writing and we will also leave it open for the public to make statements.

We appreciate Senator Helms, who is chairman of the Agriculture Committee, for authorizing this hearing for the entire committee's review, Senator Lugar, his subcommittee, of whose jurisdiction this is, and Senator Huddleston, who is also very interested, as is the entire U.S. Senate, not just those on the Agriculture Committee.

I think we have estabished a good basis by laying out all of the facts known at this time. There were some questions that were answered, and others were not. I'm sure the debate will go on.

The EPA will be provided additional information at the latter part of this week as they said in their testimony this morning and we will look forward to that information.

I am told that other congressional committees will be holding hearings on this issue and we will forward the information gathered today, to them. And of course, it was good to get all the interested parties together to hear each other in order to learn from this experience. I think it has been a productive hearing and I thank all of you for participating. We will conclude this hearing at this time.

[Whereupon, at 12:30 p.m., the committee adjourned, subject to call of the Chair.]

# APPENDIX

## STATEMENT OF EDWIN L. JOHNSON
## DIRECTOR, OFFICE OF PESTICIDE PROGRAMS
## U.S. ENVIRONMENTAL PROTECTION AGENCY

Good morning. I am glad to be here this morning to discuss with the Committee EPA's position and actions concerning the pesticide ethylene dibromide (EDB).

The principal concerns arise from reported findings of EDB residues in a variety of grain-based food products, water, and citrus fruit fumigated for quarantine purposes. Federal and state agencies as well as members of the public are concerned about the health significance of EDB residues in these foods. An additional cause for concern has arisen in several states, including Florida, where EDB residues have been found in well water. I do not come here today with answers to all the questions about EDB. However, I want to assure the Committee that EPA recognizes its responsibility to take action at the federal level to deal with EDB residues in a way that will protect public health. The Agency is working hard to meet that responsibility, but we also need to ensure that our actions are based on a responsible evaluation of EDB, based on the best information available.

It is important to point out that EPA's basic position on the risks and benefits of this chemical were clearly set out in our regulatory decisions of September 28, 1983. EDB has been used for over 35 years, and has been valuable in destroying insects in soil, grain and citrus. The balance between the risks and benefits has changed in recent years due to increased concerns about potential health effects and the development of alternatives for most major uses. Based on a detailed evaluation of health effects and economic benefits data, we concluded that for all the major uses of EDB as a pesticide, the risks of continued use outweigh the benefits and registrations should be cancelled. However, our decisions did include distinctions between the major uses of EDB which need to be understood.

For the soil fumigation use which accounted for over 90% of the use of EDB as a pesticide, we took the strongest action possible under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), an emergency suspension which immediately halted sale and distribution of EDB products. This use was already causing ground water contamination in several states. For post-harvest fumigation of citrus and tropical fruits, we issued a notice of intent to cancel to become effective September 1, 1984. This relatively short phase out period was intended to allow for commercial introduction of alternatives to EDB fumigation to meet both domestic and foreign quarantine requirements. For fumigation of stored grain and the spot fumigation of grain milling machinery, we also issued a notice of intent to cancel the use of EDB effective in 30 days. However, registrants of these uses and other interested parties appealed the cancellation notices. As the FIFRA provides, non-suspended uses may continue during cancellation proceedings. These grain uses are presumably the source of the residues being found in various foods.

As we said in our September notices, EPA's concern about EDB is not whether major pesticide uses should be allowed to continue: we feel that these uses should all stop, and EDB should be removed from the market. The issue before us now is whether public health will be endangered by the use of EDB while cancellation hearings take place. To resolve it, we need to evaluate the additional dietary exposure of the public that is likely to occur if EDB use continues during the cancellation hearings, typically a 2-year process. The law allows us to suspend the use at any time if the risks outweigh the benefits of use during that short period -- if an imminent hazard is deemed to exist. To decide this issue, we first need a good estimate of the extent to which EDB residues actually occur in the food supply. This important information has not been sufficiently available in the past. However, EPA has taken several steps to obtain this critical information.

We are gathering the necessary facts now, and are considering three actions: 1) deciding whether to issue emergency suspension notices, in addition to the cancellation notices already in place, for the uses remaining in effect; 2) recommending what residue levels are acceptable in the food supply; and 3) removing impediments to federal enforcment actions. As I will emphasize several times today, our concern about EDB is for chronic effects due to long term exposure to consumers, not for the risk of an acutely toxic effect.

Let me summarize our information on EDB residues in grain-based foods. As we stated in our September decision, in the process of evaluating the stored grain and spot fumigation uses of EDB, we found that residues did occur in grain, flour and foods made from them. However, this finding was based on limited sampling which did not indicate the actual extent of this potential problem. As part of our regulatory decision to cancel these uses, we arranged with the Food and Drug Administration (FDA) and the U.S.

Department of Agriculture (USDA) to analyze a variety of foods.

FDA's ten regional offices collected 42 samples of milk, bread, baby food and flour. Except for four wheat flour samples, EDB was not detected in these commodities. FDA also sampled stored and processed grain from facilities known to have used EDB. A majority of these samples had detectable levels of EDB with most positive findings in the low parts per billion (42 out of 53 positives below 50 ppb). There were also several samples with very high residue levels.

USDA has provided an analysis of meat samples. Of some 300 samples of beef, pork and poultry, only one pork sample had detectable levels of EDB. These data suggest that EDB residues in livestock and poultry may not be a significant source of human exposure.

Recently, Florida has provided analyses of grain-based food products such as flour, corn-meal and cake mixes taken from store shelves. These findings show detectable residues in roughly a third of several hundred samples. The majority of positive samples indicate residues from 2 to 40 parts per billion. Similar information provided by Texas generally confirms Florida's findings. Most of these off-the-shelf products with positive residue findings require further cooking prior to consumption.

We have some information to indicate that cooking does significantly reduce residue levels. The state of Florida did analyze some food products after cooking and found reductions in EDB levels ranging from 78 to 99%. Florida also sent some of their product samples to EPA and we are having further analyses of cooked products done by an independent contractor and by FDA. The Grocery Manufacturers Association (GMA) has provided data on several hundred samples of cooked foods including baked goods, hot cereals and pancakes which show signficant reductions of 78 to 99% in most samples, although a few samples showed lower reductions.

In short, the current picture of EDB residues in foods is mixed; a significant number of foods sampled contain detectable EDB residues but by no means a majority. For example, two thirds of Florida's samples of processed grain products and all of FDA's samples of products ready for consumption contained no detectable residues. We clearly need further information to assess the extent of EDB residues in particular categories of food products, since different foods comprise quite different proportions of the typical American diet. For example, wheat alone comprises about 10% of the average diet, while corn and oats together comprise less than 2%. In some regions of the country both citrus fruits and water may also be dietary routes of exposure to EDB.

Let me summarize what information we have received or are in the process of getting in order to clarify the EDB situation.

- Grain samples have been analyzed by USDA, FDA, and GMA, and additional samples requested from USDA.

- Flour samples have been analyzed by FDA, GMA, EPA's laboratory in Beltsville, Maryland, and by the States of Florida and Georgia.

- Grain-based consumer products have been analyzed by

EPA's laboratory, FDA, Florida, Georgia and Texas, and additional studies are being done by FDA and the Mid-West Research Institute.

- Fresh meat has been analyzed by USDA and a study of processed meat requested from GMA.
- Interstate shipments of citrus are being sampled by FDA and California and both Florida and FDA are analyzing fruits imported into this country.

In addition, since a number of states are also actively monitoring for EDB residues, EPA has solicited their assistance in focusing on areas where more information is particularly needed. In a letter to all state governors and in subsequent meetings with state agriculture officials, Administrator Ruckelshaus specifically asked for additional data on raw grain products, processed grain products as purchased and after preparation according to label directions, grain products such as cold cereals and oils which are eaten without further processing and other non-grain commodities still fumigated with EDB. We have also asked USDA and the states to provide as much information as possible on the extent to which EDB is still being used today in grain storage and milling operations.

We realize that we cannot wait to develop definitive information on EDB residues before proceeding to estimate risks. We have asked for as much of this additional data as available by the end of this month. Since we are in the midst of collecting and analyzing the information necessary for risk estimates, I do not want to circumvent that effort by merely guessing at the significance of the residue levels currently being reported. However, I can say several things about our general understanding of the risks of EDB residues in grain products.

The decision to cancel the grain uses of EDB is based primarily on concern for the risks of cancer evaluated for a lifetime of dietary exposure. Since we intend to cancel virtually all agricultural uses of EDB, we expect that over a finite period of time -- say five years at the outside -- exposure will decline and then cease. Even if EPA suspended the grain uses of EDB today, many treated commodities would remain in the channnels of trade for a considerable time. The decision before us now is to determine acceptable levels of exposure during this phasing-out period. The levels we recommend need to be both protective of public health and not cause massive and unnecessary disruption of the food supply. Thus, we are developing an assessment of the risks posed by continued use of the products during the period likely to be needed to conduct the cancellation proceedings. Although a limited period of exposure involves a lower level of risk, it remains to be seen whether the short-term risks estimated on the basis of new data are acceptable or whether further regulatory actions, such as suspension of the grain uses of EDB, are needed to drive the risks lower.

It is possible that certain agricultural practices and maunfacturing processes can reduce residues in treated grain. We are receiving information from the Department of Agriculture and the food processing industry which will shed some light on this. Residues in stored grain decline over time, so that unacceptable levels may be reduced by an extended storage period or by aerating the grain to allow dissipation of residues. As noted above, our preliminary information is that cooking results in about a fifteen-fold reduction in residues. Thus, when permissible levels are set in the near future, it will be clearer how many practical measures are available for achieving those levels in existing grain and food products.

Let me turn now to the problems posed by EDB contamination of ground water which has occurred in twelve counties here in Florida. The problems posed by ground water contamination are similar in terms of potential risks, but quite different in terms of the means available for dealing with those risks. Water is one route of dietary exposure to EDB. The Agency has generated estimates of the cancer risks of lifetime exposure to various residue levels in drinking water, which we have provided to the Committee. In general terms, we believe that the risks posed by EDB in drinking water at levels in the low parts per billion are roughly comparable to the risks posed by grain fumigation. In both cases we consider these estimated risk levels to be unacceptable for a lifetime of exposure. Because of our special concern for ground water, which, once contaminated, can remain so for many years after the cause is removed, we acted to suspend and cancel the uses of EDB which were leading to ground water contamination.

According to our information, the State of Florida has acted to provide alternative drinking water for approximately 500 wells found to contain EDB at or above 0.1 parts per billion. This appears to be a responsible and effective way of dealing with these potential risks. In short, the risks of EDB being reported in Florida ground water (typically 1 to 20 ppb) are probably similar to risks posed by grain products; fortunately, an effective state monitoring and response program can eliminate the need for the public to assume those risks. In addition, studies have been done which indicate that activated carbon filtration can be effective in reducing EDB residues. We understand that Florida is pursuing filtration as a means of dealing with EDB residues in ground water.

We recognize that any decision we make regarding EDB has significant international economic implications. The EPA has taken several steps to inform other governments of our action and to determine the effect on international trade. All governments world-wide have been notified about our regulatory action in September, and will be kept informed of further developments. Bilateral discussions have already been held with Japan, because they import large quantities of U.S. products treated with EDB. Through the established mechanism of the Trade Policy Committee (TPC), chaired by the Office of the U.S. Trade Representative, we will learn more about the potential effects of the EDB restrictions on other countries. In particular, we will be looking closely at the impact on the Caribbean Basin, which uses EDB on tropical fruits exported to the U.S. We will also be working with the USDA to determine the effect of EDB restrictions on U.S. grain exports.

In conclusion, we believe that the appropriate long term solution for EDB is to eliminate public exposure by ending the pesticidal uses of the chemical, and we have taken regulatory actions to do that. We are now gathering the information needed to assess current levels of public exposure and to determine what actions are appropriate to ensure that public health is protected during the time needed to eliminate the use of EDB and its residues from the food supply.

# STATEMENT

BY

JOHN R. WESSEL

OFFICE OF THE ASSOCIATE COMMISSIONER
FOR REGULATORY AFFAIRS

FOOD AND DRUG ADMINISTRATION

PUBLIC HEALTH SERVICE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

I welcome this opportunity to participate in this hearing and to discuss with you the responsibilities and activities of the Food and Drug Administration (FDA) regarding the pesticide ethylene dibromide (EDB). In my testimony I will review:

- -- FDA's statutory authority within the Federal system of laws for regulating pesticides used in the production of foods,
- -- the current regulations governing the presence of EDB residues in food, and
- -- the results of FDA surveillance of foods for residues of this pesticide.

## STATUTORY RESPONSIBILITY

The Federal Food, Drug, and Cosmetic Act requires, among other things, that food marketed in interstate commerce or imported into the United States comply with tolerances for pesticide residues established by the Environmental Protection Agency (EPA). FDA is responsible for enforcing these tolerances except in the case of meat and poultry products which are the responsibility of USDA's Food Safety and Inspection Service.

The use of pesticides in the United States is governed by the Federal Insecticide, Fungicide, and Rodenticide Act. Under this law, a pesticide prior to its distribution and use within the United States must be registered with the

EPA based on a showing that the pesticide is effective for its intended use and will not result in unreasonable adverse effects on man or the environment. Additionally, EPA has the responsibility under the Federal Food, Drug, and Cosmetic Act to set tolerances or legal maximum allowable limits on the amount of residue that may safely remain on food from the registered agricultural use of a pesticide. Pesticide residues may also be exempted from the requirement of a tolerance when the total quantity of the pesticide on food will involve no hazard to health.

In carrying out its tolerance enforcement responsibilities, FDA samples and tests foods for various pesticide residues. Food found to contain a pesticide residue in excess of tolerance or for which no tolerance or exemption from a tolerance has been established is considered adulterated and would be subject to FDA enforcement action, such as seizure, when shipped in or offered for entry into interstate commerce.

## CURRENT EDB TOLERANCE REGULATIONS

FDA's regulatory position regarding the presence of EDB residues in food is, therefore, determined by the tolerance regulations currently in effect for the registered uses of the pesticide. In explaining these regulations, a distinction must be made between the organic and inorganic chemical forms of EDB residues that may be present in food.

One of the regulations, 40 CFR 180.1006, exempts residues of organic EDB from the requirements of a tolerance when they result from the post harvest use of EDB on various grains. By law, this exemption also extends to organic EDB residues that remain in foods processed from treated grains. In other words, the regulation means that foods such as corn products, flour and cake mixes could contain any amount of organic EDB residues and would not be in violation of Federal law.

This tolerance exemption regulation was issued by FDA in 1956 when the agency had the responsibility for establishing tolerances for pesticide residues in food. This responsibility was transferred to EPA in 1970. The tolerance exemption was originally granted based on evidence that EDB would be dissipated during the processing of grains and that residues would not be present in finished foods ready for human consumption. It was not until the late 1970's that analytical methods became available that demonstrated that EDB residues could be present in finished food products. Around that time studies also showed that the organic form of EDB was carcinogenic and could cause other toxic effects.

In addition to the exemption regulation for organic EDB residues in grains, several regulations are currently in effect that specify tolerances or legal limits for residues of inorganic bromides that may be present in foods treated with EDB. These tolerances, which were also established by FDA in 1956, apply to grains, fruits, vegetables and processed foods. FDA may pursue regulatory action against these foods if the level of inorganic bromide residues exceed their corresponding tolerances.

## FDA MONITORING OF FOOD FOR EDB RESIDUES

Beginning in 1978, FDA started to monitor food for organic EDB residues. This was also around the time EPA began its review of the registered uses of EDB in light of new information on the chemical's toxicity. I will summarize the results of FDA's monitoring activities, some of which were initiated when EPA asked FDA to gather information on levels and the incidence of organic EDB residues in certain foods.

In 1978, FDA conducted a survey consisting of 570 samples of fruits, vegetables and peanuts for residues that might result from soil fumigation uses of certain pesticides, including EDB. Organic EDB residues were not detected in any of the commodities sampled. The FDA limit of determination at that time was approximately 20 parts per billion (ppb).

In 1979, the agency began monitoring for residues of several chemical fumigants in grains which could have received post harvest treatment. Of the 161 raw grain samples tested in 1979 and 1980, 20 were found to contain EDB residues at levels as high as 3000 ppb.

In 1981 and 1982, FDA's grain sampling for fumigants continued. Of the 51 samples tested, 11 were found to contain EDB with levels ranging up to 2200 ppb in unprocessed wheat. One sample of raw milo grain contained 38,100 ppb.

At EPA's request, FDA conducted a survey in 1981 which consisted of 219 samples of citrus with a history of known post harvest EDB treatment. Ninety-eight percent of the citrus samples tested were found to contain EDB residues. The highest level found was 14,800 ppb in imported tangerines, which were fumigated at the port of entry where FDA collected the sample.

More recently FDA carried out a limited survey of bread, flour, milk and infant cereals collected randomly from various parts of the United States. Four samples of flour were found to contain organic EDB residues ranging in levels from 2 to 8 ppb. All the other samples contained no detectable residues at a method sensitivity of 1 ppb.

At the request of EPA, FDA also sampled grain and grain products from seven mills in different parts of the country where EDB was believed to be used as a fumigant. Results from this survey showed that most of the samples of raw and processed grains contained detectable residues. The positive samples contained levels ranging from about 1 ppb to 30,700 ppb, which was found in unprocessed oats.

Concurrent with the mill survey, FDA conducted a survey of grain, citrus and distillery by-products that might be used for animal feeds. Of the 44 samples tested, EDB residues were found in two grain by-product samples at 7 and 18 ppb.

In November, when FDA was alerted by State officials in Florida regarding their findings of EDB residues in processed foods, the agency collected samples of the same types of foods to determine if they were in compliance with current tolerances for inorganic bromide residues. All results fell well below the tolerance levels. Additionally, the State of Florida provided FDA with duplicate samples of processed foods that the State's Agriculture and Consumer

Services laboratory found to contain organic EDB residues. FDA analytical results confirmed Florida's findings.

Last week, FDA issued priority sampling assignments to its field offices to collect samples of imported and domestic citrus and citrus juices for organic EDB analysis. In this survey, positive EDB findings in whole fruit samples will be followed by separate EDB analysis of the citrus peel and the edible pulp. This determination should permit EPA to make a more accurate assessment of actual dietary exposure to EDB from treated citrus.

Additionally, FDA is currently conducting a study developed in cooperation with EPA to determine the fate of EDB residues on cooking processed grain products. Thes study is intended to validate other studies which indicate that EDB residues decrease substantially when subjected to normal cooking temperatures. The results of the study should be available to EPA later this week.

Finally, FDA scientists are working with EPA in compiling all available EDB monitoring data including the results obtained by the State of Florida's testing activities. This priority effort is aimed at developing a baseline for updating EPA's estimate of the level of dietary exposure to EDB which, in turn, is to be used by EPA to reassess the level of risk that might be associated with current levels of EDB in the food supply.

Thank you Madame Chairman. That concludes my statement. If you and the members of this Committee have any questions, I will try to answer them.

# STATEMENT OF
# U.S. DEPARTMENT OF AGRICULTURE
# ON
# ETHYLENE DIBROMIDE

Ethylene dibromide (EDB) has been in use since 1948. In 1974, the National Cancer Institute issued a preliminary notice that EDB appeared to cause cancer in laboratory animals at relatively high dosage levels. Further studies confirmed that EDB posed risks of producing tumors, genetic mutations, and adverse reproductive risks. In December 1977, EPA began a review of risks and benefits and issued a statement which described the health risks of EDB. EPA continued to monitor EDB, and in June 1983 it found ground water in California had been contaminated by EDB. Shortly thereafter, wells in Hawaii and Florida were also found to have been contaminated, leading EPA to issue an emergency ban on EDB as a soil fumigant.

EDB is a halogenated hydrocarbon used primarily as an additive in leaded gasoline. Annual EDB production is estimated at 300 million pounds. More than 90 percent is used in gasoline as an additive to prevent lead deposits in the engine. In 1983, approximately 5 to 7 percent was used for agricultural purposes.

The major agricultural use of EDB was for soil fumigation to protect crops such as peanuts, soybeans, vegetables, and pineapple from nematodes until this use was banned by the Environmental Protection Agency (EPA) in September 1983.

EDB has also been used as an on-farm grain fumigant and to rid grain milling equipment of insects. The Millers National Federation has indicated that its member organizations have voluntarily stopped using EDB as a spot mill fumigant. Current information indicates these uses have decreased significantly.

Quarantine treatment is required for fruits and vegetables exposed to fruit flies. EDB is the most widely used registered chemical fumigant for postharvest control of Mediterranean, Mexican, oriental, melon, and Caribbean fruit flies. There is no alternate effective treatment that will provide American agriculture the protection needed to prevent the spread of all these destructive pests. Citrus fruits from Florida, Texas, and Mexico must be fumigated with EDB prior to their being shipped to California, Arizona, Texas, New Mexico, and Japan. The loss of EDB would seriously affect the commerce of the domestic growers in the United States as well as many foreign countries, resulting in large economic losses. Less than 100,000 pounds of the chemical is used for this purpose domestically, which represents 0.3 percent of the total annual EDB production.

USDA believes that alternatives are available to EDB for soil fumigation, grain treatment and spot mill fumigation; although some of these alternatives are not as effective or economical as EDB itself. However, as stated above, alternatives to EDB are not available at this time for fruit and vegetable quarantine treatment. USDA has for a number of years been cooperating with industry and States to test alternative technologies to control fruit flies in the impacted commodities. This has resulted in Japan and California approving a cold treatment procedure on citrus from Florida. However, this cold treatment does not have application to all citrus and tropical fruits which will require separate technologies for each pest and commodity. Research is continuing to evaluate other chemical fumigants, various temperature exposures and mixtures of gases. Irradiation treatment does not appear to be a viable alternative in the near future due to the requirement for regulatory approval, equipment availability, facility construction, and potential problems with consumer acceptance.

A nonchemical approach, currently employed in Texas and under development in Florida, is the management of fruit flies in the field that will lead to a certification of freedom from infestation.

# STATEMENT OF
# SHERWIN GARDNER
# VICE PRESIDENT, SCIENCE & TECHNOLOGY
# GROCERY MANUFACTURERS OF AMERICA, INC.

Good morning, Madam Chairman. I am Sherwin Gardner, Vice President, Science and Technology of the Grocery Manufacturers of America, Inc. (GMA). The GMA is a trade association representing the leading manufacturers of grocery products in the United States. The membership of GMA is composed of 130 companies which employ over 2.5 million people and account for over $200 billion in total annual sales. Prior to joining GMA in 1979, I served as Deputy Commissioner of the U.S. Food and Drug Administration for 7 years.

## I. Overview

GMA and its member companies have cooperated with the Environmental Protection Agency in providing it with laboratory data that effectively indicates that ethylene dibromide (EDB) levels in grain derived produts are substantially reduced through processing and cooking techniques. The data indicate that EDB levels are reduced to such minute levels in food products as consumed, that there is no danger to the American consumer. I am submitting our report of the compilation and analysis of these data to the Committee for the record.

The findings of experts in the fields of toxicology and risk assessment have identified fundamental deficiencies in the National Cancer Institute tests on EDB, which were used by the EPA to estimate risks. Their evaluation of the NCI tests complements our findings of negligible EDB levels, and offers a professional, scientific analysis of the inadequacies of the NCI test results. Reliable techniques for quantitative risk assessment have been outlined by qualified scientists, which help to point out the unreliability of the NCI study of EDB. A valid risk assessment on the potential risks from exposure to EDB containing grain products , as consumed, must be conducted before taking actions to remove products from the marketplace. GMA has undertaken a risk assessment study of EDB in grain based products, and have committed to providing it to the EPA. Our preliminary findings from this work show that existing food products containing minute levels of EDB present an insignificant health risk, and therefore any actions against grain products are inappropriate and unwarranted.

## II. Summary of GMA Compilation and Analysis of Data

EDB is an effective pesticide that has been used for the past 35 years as a fumigant in imilling operations and for bulk stored grains. Today, EDB is the subject of controversy and is described by some as a serious health hazard to the public in the form of grain based foods on grocery store shelves. However, this viewpoint is based on questionable testing, yielding data of corresponding uncertainty and doubtful utility.

Following Florida's recent actions removing removing products from sale, and in cooperation with EPA's interest in establishing national guidance concerning grain products, GMA asked its member companies to conduct laboratory tests of grain and foods for EDB residues. The results of these tests will assist EPA in the conduct of a scientific, meaningful assessment of the potential risk arising from the dietary intake of EDB in food products. GMA has analyzed the results obtained from these laboratory tests and supplied them to the EPA.

Each participating GMA company carried out its own sampling and analysis program to develop data. Samples were taken from existing stores of grain and flour or mix, and a variety of finished foods--bread, cookies, pasta, etc.-- were prepared in order to test the condition of foods as consumed. The tests were focused on four areas in order to estimate dietary exposure to EDB:

1) EDB residues in raw grain commodities
2) The effect of processing on EDB residues, in the course of converting raw grain commodities into flour, meal and other milled products.
3) The effect of baking and other cooking techniques on EDB residues in foods containing grain, or grain-derived products.
4) EDB residues in foods as consumed.

With regard to the first area, EDB analyses were performed on raw grains from bulk storage and the results show that 133 out of the 264 samples analyzed, or 50%, contained levels less than 1 ppb. The median EDB level for the 264 samples is calculated to be less than 1 ppb. Specifically, the results for wheat, which represents over 10% of the U.S. diet, show that 47 of 102 samples, or 46%, contained levels of EDB below 1 ppb. The median EDB level for the 102 wheat samples is 1.2 ppb. These results indicate the very low levels of EDB residues in most unprocessed grain.

Second, a controlled experiment was run to obtain an estimate of the reduction of EDB levels in grain that result from the milling of wheat. Wheat was specially fumigated for 25 hours, resulting in artifically high experimental levels of EDB. In normal milling operations, the interval between treatment and milling is considerably longer. After commercial processing of the grain in a pilot plant, the flour obtained showed a 95% reduction of EDB. Because of the larger time intervals after EDB treatment in normal commercial operations, we would expect the reductions to be somewhat less, but still extensive.

From this point, flour from this experiment was baked into bread, indicating an additional 95% reduction in levels of EDB as a result of baking. This controlled experiment from wheat to bread, showed a total reduction of EDB greater than 99%.

Third, several GMA member companies conducted laboratory tests using materials with experimentally-enhanced levels of EDB in order to improve analytical accuracy. Flour and cake mix with enhanced levels of EDB were baked into products such cakes, cookies, or bread. The median reduction of the artificially high EDB level in these experimental products is between 92%-99%, also indicative of the substantial reduction of EDB resulting from cooking techniques.

Our data show that EDB levels in corn products are similarly reduced by normal cooking, with a median reduction of EDB in products tested between 94% and 99%.

Finally, and most important, EDB analyses were performed on a number of grain-derived products prepared as they are normally eaten. The results indicate that 153 out of 192 product samples, or 79%, contained levels of EDB below 1 ppb. The median EDB level for the 192 samples is less than 1 ppb.

The data reported to this point demonstrate substantial reductions in the EDB residues as grain is milled, processed, and cooked. Thus, we conclude that risk assessments should be based on exposure to EDB in products as eaten, taking into account consumption patterns of the various types of products produced from each type of grain, as well as appropriate exposure estimtes for the various grains. The latter data are contained in the GMA compilation.

GMA is continuing to receive test results from its member companies and will cooperate with the EPA and other government agencies in conducting a scientific risk assessment for EDB.

## III. Scientific Experts Express Doubts About EDB Risk

In addition to our test findings, GMA is suspect of the methods used in the National Cancer Institute Bioassay on EDB upon which the EPA based its risk estimates published on October 11, 1983. Our concern is shared by two experts in the field of toxicology and risk assessment, who have expressed their reservations regarding the deficiencies of the techniques used in these tests. Dr. Joseph V. Rodricks, a nationally recognized independent consultant (Ph.D. in biochemistry), has performed numerous risk assessments concerning naturally occurring and man-made carcinogens over the past 20 years, as an employee of the Food and Drug Administration and in a private consulting business. Dr. Rodricks is a member of the American College of Toxicology and a member of the Board of Directors of the Academy of Toxicological Sciences. Dr. Seymour Freiss (Ph.D. in chemistry) is former president of the International Union of Toxicologists, and former president of the American Society of Toxicology. Dr. Friess is a member of numerous scientific organizations and has been a research chemist for more than 30 years, first with the United States Department of the Navy and then with a consulting firm. He has also performed numerous quantitative risk assessments.

During testimony before U.S. District Court of Northern Florida, on January 12, 1984, Dr. Rodricks stated "that insofar as it pertains to grain products, the Environmental Protection Agency has produced an extreme, saying there is a risk to human health." The "extreme" referred to here is the risk estimate EPA adopted as a result of its study on the NCI Bioassay on EDB. Dr. Rodricks described in detail the Bioassay's defects. First, the use of tube feeding (gavage) rather than conventional dietary exposure, which is criticized by both experts. The gavage procedure consists of inserting a tube into the stomach of the laboratory animal, in this case a rat, and administering doses of EDB through the tube. Dr. Rodricks contended that the possibility of cancerous tumors developed from the gavage method itself rather than from EDB. Dr. Friess stated that the gavage method cannot be relied upon for quantitative risk assessment for cancer in humans "because it has very serious design and execution flaws." Dr. Friess explained that the purpose of the procedure was not designed for risk assessment, but to determine "whether the chemical has the potential of producing cancer in that animal." He contends NCI's gavage study on EDB cannot be relied upon for quantitative risk assessments for cancer in humans.

Second, Dr. Rodricks recognized that the dosing procedures applied to test animals was highly irregular. The doses administered during the gavage test were extremely high in the initial stages; attempts were made to compensate by changing or stopping the dosage for a period of time to achieve an average dosage over the lifetime of the rats. Dr. Rodricks states, "The result is that there is great uncertainty in that experiment about what dose level the animals actually got. This is important because the dose level they got, the quantitative dose of EDB, is a critically important factor for risk assessment. It is uncertain in this experiment."

Dr. Friess testified that the NCI Bioassay was so flawed that a dose response relationship for cancer cannot be established. He also testified that, based on the NCI data, he could not conclude that EDB is a carcinogen in humans.

Dr. Rodricks identified several other defects in the experiment, including the fact that the experiment was foreshortened because there was substantial early mortality among the rats due to the early high doses, the use of the very conservative and untested method of gauging exposure (one-hit model with Weibull timing), and the assumption that everyone is exposed to grain products containing 31 ppb of EDB after cooking everyday of their life, a figure that is "demonstratively in gross error."

Dr. Rodricks further testified that FDA and EPA generally consider risks to be negligible if they are in the range of one per hundred thousand to one per one million. Dr. Rodricks concluded that both his own estimate and the EPA's Position Document 2-3 estimate for three years of exposure are well below what the federal agencies generally consider to be a negligible risk. The revised EPA Position Document 2-3 estimate for seventy years of exposure is only slightly above what is considered negligible.

In addition, Dr. Rodricks holds that an assessment of risk regarding food products should be focused in the prepared or cooked stage, which "is really nothing more than common sense." .

Dr. Rodricks stated that it was his understanding that the State of Florida is acting at the level of the intermediate stage products, rather than prepared foods to be consumed. "I have seen no evidence that Florida has considered the risks at all." According to Dr. Rodricks, there is no useful purpose in issuing stop-sale orders on products in grocery stores.

In conclusion, the GMA strongly urges other state governments to refrain from implementing stop-sale orders on food products before a responsible risk assessment of EDB in food as consumed is determined. Our data, which continues to come in and will be furnished to EPA, clearly demonstrates that EDB residues are significantly reduced through processing and cooking techniques. EDB in grain-derived food products does not represent a health hazard to the general public, and our food supply remains one of the safest in the world.

The GMA and the food industry are committed to maintaining the safety and wholesomeness of the U.S. food supply and we will continue to assist EPA and other government agencies in determining a valid risk assessment for EDB in food products.

Madam Chairman, this concludes my formal statement. I will be glad to answer any questions you may have.

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January 16, 1984

Dr. Edwin L. Johnson
Director
Office of Pesticide Programs
Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

Dear Dr. Johnson:

The enclosures to this letter provide the data on EDB residues in food products from grain, as we committed to you in our letter of December 30, 1983. More than 1000 analyses of grain, flour and ready to eat products were conducted to develop the data.

Particular effort was made to obtain information on the extent to which EDB is removed from food manufacturing and cooking processes. We believe the data demonstrate that, depending on the product, most or all EDB residues are removed in these processes such that any minute amounts that may remain pose an insignificant health risk.

In addition to the data enclosed, we are preparing a risk assessment of exposure to EDB through consumption of grain products. Our preliminary findings from this work indicate that any health risks from consumption of EDB in grain for a limited time, e.g., a three year period, are insignificant. This assessment is based on estimates of grain products as consumed, and utilizes the information being provided today. We expect to have this assessment by January 20 and will share it with you.

We plan to meet with you to review the data package on Tuesday, January 17, and to respond to questions you may have about it. It is our expectation that there will be need for continued communication between us as you review this data and other similar information being developed by or for the EPA in order to address any scientific and technical issues that arise. We will continue to keep in touch with you in order to address these matters in a timely way.

Sincerely,

Sherwin Gardner
Sherwin Gardner

Enclosures

# REPORT OF
# ETHYLENE DIBROMIDE
# RESIDUES IN FOOD
# PRODUCED FROM GRAIN

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A compilation and analysis of data
obtained from laboratory analyses of raw grains, flour,
mixes, meals, uncooked products and foods as eaten

Prepared by

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## ETHYLENE DIBROMIDE RESIDUES IN FOOD

### I - Introduction

The Environmental Protection Agency [EPA] gave notice on September 28, 1983, of its intent to cancel registration of pesticide products containing ethylene dibromide [EDB], under section 6 of FIFRA.

The EPA notice proposed the cancellation of EDB preparations for the post-harvest fumigation of bulk-stored grains (wheat, corn, sorghum, barley, rye, rice and oats), and for the spot fumigation of milling machinery used to convert grain into flour, meal and other products.

EDB, for the past 35 years, has been an effective pesticide, used in combination with carbon tetrachloride and/or carbon disulfide as a liquid fumigant for bulk-stored grains containing between 1.2% and 5% EDB, or used in combination with methyl bromide for the spot fumigation of milling machinery as a gaseous mixture containing 70% EDB.

EPA expressed concern about the dietary exposure to EDB from these uses, and indicated it was gathering additional information concerning such dietary exposure potential.

The Grocery Manufacturers of America, Inc., [GMA] is the trade association representing the leading manufacturers of food and other grocery products sold in the retail outlets throughout the United States. Our member companies employ over 2.5 million people and have total annual sales in excess of $200 billion.

The food industry and GMA are committed to ensuring the safety, wholesomeness and nutritional value of the American food supply. As part of this commitment, GMA has requested its member companies to assist in the determination of a meaningful assessment of the potential dietary intake of EDB resulting from grain products.

Specifically, GMA has asked its member companies to supply data concerning the following points in order to estimate the dietary exposure to EDB:

[a] EDB residues in raw grain commodities,

[b] Effect of processing on these EDB residues, in the course of converting raw grain commodities into flour, meal and other milled products,

[c] Effect of baking and other cooking and/or preparation techniques on the EDB residues in food containing grain, or grain derived products,

[d] EDB residues in foods as consumed.

The following report to EPA presents a compilation of the data gathered by the GMA from its member companies in response to the above request, and an analysis of the significant findings.

While additional data are in the process of being developed, and further results will be available in the next two or three weeks, GMA has considered it appropriate to submit the present report to EPA, because it provides information and clarification of some of the key issues relating to the dietary exposure potential of EDB resulting from grain products.

It is GMA's intent to update EPA on a timely basis as additional data are developed. It is GMA's further intent to provide EPA with an assessment of the potential risks associated with the general population's dietary exposure to EDB arising from uses on grains.

GMA is most willing to have its scientific staff and experts, as well as those of its member companies, meet with EPA counterparts to review, clarify and discuss the data presented in this report, as well as any need for additional data to be developed in connection with these issues.

## II - Methodology

In developing the data each GMA company carried out its own sampling and analysis program. The data reported here are compilations of those individual submissions. Although the data are extensive, they are not necessarily representative of all of the commodities and products in each category. The data are typical of the kinds of products and ingredients encountered by each company.

Modifications of the Rains and Holder [J. Assoc. Off. Anal. Chem. 64:1252, 1981] method for analysis of EDB were used to assay these samples. Time did not permit the cross-calibration of the various laboratories, so that the reliability of the data is the responsibility of the company submitting it.

1 ppb is accepted as the detection limit for EDB analyses, and no levels are reported below 1. For calculation purposes all values below 1 ppb, including non-detectable levels, were calculated at the conservative 0.75 ppb level.

## III - Consumption Estimates

Of all grains, wheat represents the largest component of the U.S. diet, being seven times the consumption of the second largest - corn.

Because of the dietary importance of wheat, over 10% of the U.S. diet, most of the data generated by GMA focuses on wheat and wheat-containing food products. Most of the wheat consumed in the United States is converted into flour prior to consumption. The dietary intake of wheat is principally through flour-based products. A summary of flour usage is given in the following table:

Table 1

ANNUAL FLOUR CONSUMPTION

| Use | Billions of lbs | % of Total |
|---|---|---|
| Commercial Bread & Rolls | 14.0 | 49 |
| Commercial Cookies, Crackers & Pretzels | 3.9 | 14 |
| Commercial Cakes Sweet Goods | 2.8 | 10 |
| Pasta | 2.5 | 9 |
| Home use of Flour | 2.0 | 7 |
| Flour used in mixes & other foods | 1.7 | 6 |
| Export | 1.6 | 5 |
| Totals | 28.5 | 100 |

## IV Reductions of EDB in Wheat Products During Processing and Cooking

Analyses carried out by GMA companies demonstrate that the EDB levels of wheat, flour, and flour mixes are substantially reduced by the processes leading to foods as eaten.

### A. Milling Effects

A controlled experiment was run to obtain an estimate of the losses of EDB that result from the milling of wheat. Wheat was specially fumigated for 25 hours, resulting in an artifically high experimental level of EDB. In normal milling operations the interval between treatment and milling is considerably longer. The experimentally-treated wheat was subjected to milling in a pilot plant representative of commercial processes. Flour was obtained showing a 95% reduction of EDB [Table 2]. Because of the longer time interval after EDB treatment in normal commercial operations, we would expect the losses in milling operations to be less, but still extensive. Flour from this experiment was baked into bread, showing a further 95% reduction in levels of EDB. This controlled experiment indicated a total reduction of EDB, from wheat to bread, of greater than 99%.

## Table 2

## EXPERIMENTAL LABORATORY TESTS TO DETERMINE REDUCTION OF EDB DUE TO PROCESSING

| Processing Stage | Fumigated Test* ppb EDB | Control Test [unfumigated] ppb EDB |
|---|---|---|
| Wheat | 17,816 | 18 |
| Tempered Wheat | 8,982 | — |
| Flour | 967 | (1 |
| Bread | 48 | (1 |

* fumigated for 25 hours.
( is used for "less than"

### B. Cooking Tests on Consumer Products

Normal cooking reduces the EDB level in wheat products. Cooking tests on commercial-type products were carried out with consistently large reductions in EDB content. The median reduction of EDB in wheat products is between 78% and 99%. The data are shown in the following table:

## Table 3

## REDUCTION OF ETHYLENE DIBROMIDE DURING COOKING
### Wheat Products

| Flour or Mix ppb EDB | Consumer Food ppb EDB | % EDB Reduction |
|---|---|---|
| 55 | (1 [biscuits] | )99 |
| 11.4 | (1 [bread] | 93-99 |
| 8.0 | (1 [bread] | 91-99 |
| 17.7 | (1 [bread] | 96-99 |
| 2.0 | (1 [bread] | 62*-99 |
| 7.5 | (1 [bread] | 90-99 |
| 21.5 | (1 [bread] | 97-99 |
| 2.4 | (1 [bread] | 69*-99 |
| 29.9 | (1 [bread] | 97-99 |
| 2.6 | 2.1 [bread] | 19* |
| 6.2 | 1.5 [bread] | 75 |
| 1.3 | 1.9 [bread] | * |
| 13.0 | 3.8 [bread] | 70 |
| 8.3 | 3.0 [bread] | 64 |
| 7.6 | 3.7 [bread] | * |
| 10.8 | 1.0 [bread] | 90 |
| 2.8 | 1.1 [bread] | 60* |
| 1.9 | (1 [bread] | 61*-99 |
| 1.9 | (1 [bread] | 61*-99 |
| 1.9 | (1 [bread] | 61*-99 |
| 3.8 | (1 [bread] | 80-99 |
| 3.8 | (1 [bread] | 80-99 |
| 6.1 | (1 [bread] | 88-99 |
| 2.4 | (1 [bread] | 69*-99 |

| Flour or Mix ppb EDB | Consumer Food ppb EDB | % EDB Reduction |
|---|---|---|
| 21.1 | (1 [bread] | 96-99 |
| 7.5 | (1 [bread] | 90-99 |
| 11.6 | 1.8 [bread] | 84 |
| 7.2 | (1 [bread] | 90-99 |
| 30.4 | (1 [bread] | 98-99 |
| 3.4 | 1.2 [bread] | 64* |
| 2.4 | (1 [rolls] | 69-99 |
| 5 | (1 [cookies] | 85-99 |
| 13 | (1 [cookies] | 94-99 |
| 75 | (1 [cookies] | 99 |
| 261 | 15.5 [cookies] | 94 |
| 291 | 13.8 [cookies] | 95 |
| 0.5 | (1 [cake] | * |
| (2 | (1 [cake] | * |
| 8 | 2.4 [cake] | 70 |
| 2 | (2 [cake] | * |
| 4 | (1 [cake] | 81-99 |
| (2 | (1 [cake] | * |
| 450 | (1 [cake] | )99 |
| 31 | (1 [cake] | 97-99 |
| 19 | (1 [cake] | 96-99 |
| 12 | (1 [cake] | 94-99 |
| 3 | 2 [cake] | 33* |
| 64 | 11 [cake] | 83 |
| 64 | 16 [cake] | 75-99 |
| 64 | 4 [cake] | 94 |
| 64 | (1 [cake] | 99 |
| 30 | 4 [cake] | 87 |
| 30 | 8 [cake] | 73-99 |
| 30 | (2 [cake] | 93-99 |
| 20 | 2 [cake] | 90 |
| 20 | (1 [cake] | 96-99 |
| 20 | (1 [cake] | 96-99 |
| (1 | (1 [cake] | * |
| 33 | (1 [cake] | 98-99 |
| 90 | 32 [cake] | 64 |
| 5.1 | (1 [cake] | 85-99 |
| 5.2 | (1 [cake] | 86-99 |
| 5.1 | (1 [cake] | 85-99 |
| (1 | (1 [cake] | * |
| (1 | (1 [cake] | * |
| (1 | (1 [cake] | * |
| (1 | (1 [cake] | * |
| (1 | (1 [cake] | * |
| (1 | (1 [cake] | * |
| (1 | (1 [cake d-nut] | * |
| (1 | (1 [cake d-nut] | * |
| (1 | (1 [cake d-nut] | * |
| (1 | (1 [cupcake] | * |
| 1.8 | (1 [oatmeal brd] | 59*-99 |
| 3.2 | (1 [doughnuts] | 77-99 |
| 3.2 | (1 [doughnuts] | 77-99 |
| 3.2 | (1 [doughnuts] | 77-99 |
| 5.15 | (1 [potato roll] | 85-99 |
| 5.15 | (1 [potato roll] | 85-99 |
| 5.15 | (1 [potato roll] | 85-99 |
| 4.8 | (1 [pumpernickle bread] | 84-99 |

| Flour or Mix ppb EDB | Consumer Food ppb EDB | % EDB Reduction |
|---|---|---|
| 4.8 | (1 [pumpernickle bread] | 84-99 |
| 4.8 | (1 [pumpernickle bread] | 84-99 |
| 9.5 [wh germ] | 1 [cooked wh gm] | 95 |
| 10.8 [wh germ] | 1 [cooked wh gm] | 94 |
| pasta | cooked pasta | |
| 13.3 | 1.1 [macaroni] | 99 |
| 5.2 | (1 [macaroni] | 86-99 |
| 9.4 | (1 [macaroni] | 84-99 |
| 4.2 | (1 [macaroni] | 82-99 |
| 1.8 | (1 [macaroni] | 58*-99 |
| 1.5 | (1 [macaroni] | 50*-99 |
| 1.9 | (1 [noodles] | 61*-99 |
| 1.4 | (1 [noodles] | 46*-99 |
| 1.3 | (1 [noodles] | 42*-99 |
| (1 | (1 [spagetti] | * |
| 15.9 | (1 [spagetti] | 95-99 |
| 11.0 | (1 [spagetti] | 93-99 |
| 1.3 | (1 [spagetti] | 42*-99 |

( is used for "less than"
) is used for "more than"
* These apparently low reductions result from very low levels of EDB in the flour, mix, or uncooked product.

## C. Cooking Experiments

Several member companies of GMA carried out laboratory tests using materials with experimentally-enhanced levels of EDB in order to improve analytical accuracy. Flour or Cake Mix with enhanced levels of EDB were baked into products such as cakes, cookies, or bread. The median reduction of EDB in the experimental products tested is between 92% and 99%. These results also show substantially large reductions of EDB during cooking [Table 4].

### Table 4

### EXPERIMENTS TO MONITOR EDB REDUCTION DURING COOKING IN SAMPLES CONTAINING EXPERIMENTALLY-ENHANCED LEVELS OF EDB

| Flour or Mix ppb EDB | Consumer Food ppb EDB | % EDB Reduction |
|---|---|---|
| flour | | |
| 62* | (1 [biscuits] | 99 |
| 133* | 3 [biscuits] | 98 |
| 59* | 2.6 [bread] | 96 |
| mixes | | |
| 66* | (1 [cake] | 99 |
| 519* | 43 [cake] | 92 |
| 115* | 12 [cake] | 90 |
| 674* | 92 [cake] | 86 |
| 102* | 29 [cake] | 72 |
| 188* | 46 [cake] | 76 |

| | | |
|---|---|---|
| 61* | 12 [cake] | 80 |
| 58* | 15 [cake] | 74 |
| 9.9* | (1 [cake] | 92-99 |
| 9.8* | (1 [cake] | 92-99 |
| 9.9* | (1 [cake] | 92-99 |
| 50.8* | 1.6 [cake] | 97 |
| 52.8* | 1.9 [cake] | 96 |
| 50.8* | 2.4 [cake] | 95 |
| 66* | (1 [cupcake] | 99 |
| 519* | 47 [cupcake] | 91 |
| 61* | 10 [cupcake] | 84 |
| 58* | 10 [cupcake] | 83 |
| 58* | 9 [cupcake] | 84 |
| pasta | | |
| 19* [dry] | (1 [cooked] | 96-99 |
| 19* [dry] | (1 [cooked] | 96-99 |

( is used for "less than"
) is used for "more than"
* samples experimentally enhanced with EDB in the laboratory

## V - EDB Reductions in Corn Products

Normal cooking reduces EDB levels in corn products similar to the reductions in wheat products shown in Section IV. The median reduction of EDB in the corn products tested is between 94% and 99%. These substantially large reductions in EDB levels are shown in the following table:

Table 5

REDUCTION OF ETHYLENE DIBROMIDE DURING COOKING
Corn Products

| Corn Meal/Grits ppb EDB | Consumer Food ppb EDB | % EDB Reduction |
|---|---|---|
| 990.0 [corn meal] | 17 [corn muffin] | 98 |
| 50.0 [corn meal] | (1 [corn muffin] | 98-99 |
| 8.6 [corn meal] | 1 [corn muffin] | 88 |
| 11.0 [corn meal] | (1 [corn muffin] | 93-99 |
| 14.0 [corn meal] | (1 [corn muffin] | 95-99 |
| 17.0 [corn meal] | 1.3 [corn muffin] | 92 |
| 20 [h/p mix] | 2.5 [hush puppy] | 88 |
| 520 [h/p mix] | 1.6 [hush puppy] | )99 |
| 681 [h/p mix] | (1 [hush puppy] | )99 |
| 534 [h/p mix] | (1 [hush puppy] | )99 |
| 595 [h/p mix] | 1.2 [hush puppy] | )99 |
| 5.9 [grits] | (1 [quick grits] | 87-99 |
| 12 [grits] | (1 [quick grits] | 94-99 |
| 15 [grits] | (1 [quick grits] | 95-99 |
| 8.8 [grits] | (1 [quick grits] | 91-99 |
| 2.2 [grits] | (1 [quick grits] | 66-99 |
| 8.3 [grits] | (1 [quick grits] | 91-99 |

( is used for "less than"
) is used for "more than"

## VI - Finished Products As-Consumed

EDB analyses were performed on a number of grain derived products prepared as they are normally eaten. The results [Table 6-attached] show that 153 out of 192 product samples, 79%, contained levels of EDB below 1 ppb. The median EDB level for the 192 samples is less than 1 ppb, with a range of )1 - 32 ppb.

## VII - Intermediate Grain Products

EDB analyses were performed on grain derived products such as flour, cake mix, and corn meal as they appear on the store shelf and before cooking. The results [Table 7-attached] show that 183 out of 554 product samples, 33%, contained levels of EDB below 1 ppb. The median EDB level for the 554 samples is less than 3 ppb, with a range of )1 - 990 ppb.

The results for flour [Table 7] show that 37 out of 278 product samples, 13%, contained levels of EDB below 1 ppb. The median EDB level for the 278 samples is less than 5 ppb, with a range of )1 - 450 ppb.

## VIII - Raw Grains

EDB analyses were performed on raw grains taken from bulk storage. The results [Table 8-attached] show that 133 out of 264 samples of all grains, 50%, contained levels of EDB below 1 ppb. The median EDB level for the 264 samples is less than 1 ppb, with a range of )1 - 26,600 ppb.

The results for wheat [Table 8] show that 47 of 102 samples, 46% contained levels of EDB below 1 ppb. The median EDB level for the 102 wheat samples is 1.2 ppb., with a range of )1 - 650 ppb.

## IX - Disappearance of EDB-Treated Wheat

GMA estimates that, based on present consumption rates and patterns, and assuming no further use of EDB for bulk wheat fumigation, the disappearance of EDB-treated wheat would be as shown in the following table:

Table 9

| Year | % of U.S. Wheat Stocks Treated with EDB |
|---|---|
| 1983 | 40 |
| 1984 | 20 |
| 1985 | 10 |
| 1986 | 5 |
| 1987 | 0 |

Our experience indicates that supplies of corn treated with EDB would disappear slightly more rapidly, in approximately three years.

## X - Conclusions

Information regarding annual flour consumption shown in Section III demonstrates that it is appropriate to weigh exposure estimates for the various types of products produced from each grain,as well as the relative consumption patterns for the various grains, in making risk assessments.

Taken together, the data reported in Sections IV - VII demonstrate substantial reductions in EDB residues as grain is milled, processed, and cooked. Thus, risk assessments should be based on exposure to EDB in products as eaten. In addition, any contemplated governmental actions must take into account the reductions in EDB during processing and cooking.

The data in Sections VIII & IX indicate that a significant portion of the nation's grain supply contains EDB, and, assuming no further use of EDB, it will take several years for this grain to be used up.

## Table 6

## EDB LEVELS IN PRODUCTS
### Ready to be Consumed Items

| GMA # | Product | ppb EDB |
|---|---|---|
| 1 | Biscuits - Lab Baked | (1 |
| 2 | Bread - commercial | 1.8 |
| 3 | Bread - commercial | (1 |
| 4 | Bread - commercial | (1 |
| 5 | Bread - commercial | 7.4 |
| 6 | Bread - commercial | (1 |
| 7 | Bread - commercial | 1.1 |
| 8 | Bread - commercial | (1 |
| 9 | Bread - commercial | (1 |
| 10 | Bread - commercial | (1 |
| 11 | Bread - commercial | (1 |
| 12 | Bread - commercial | (1 |
| 13 | Bread - commercial | (1 |
| 14 | Bread - commercial | (1 |
| 15 | Bread - commercial | (1 |
| 16 | Bread - commercial | (1 |
| 17 | Bread - commercial | (1 |
| 18 | Bread - commercial | (1 |
| 19 | Bread - commercial | (1 |
| 20 | Bread - commercial | (1 |
| 21 | Bread - crack wheat | (1 |
| 22 | Bread - multi grain | (1 |
| 23 | Bread - oatmeal | (1 |
| 24 | Bread - sprouted wheat | (1 |
| 27* | Bread - lab baked | 1.1 |
| 30 | Bread - lab baked | (1 |
| 31 | Bread - lab baked | (1 |
| 32 | Bread - lab baked | (1 |
| 33 | Bread - lab baked | (1 |
| 34 | Bread - lab baked | (1 |
| 35 | Bread - lab baked | (1 |
| 36 | Bread - lab baked | (1 |
| 37 | Bread - lab baked | (1 |
| 38 | Bread - lab baked | 2.1 |
| 39 | Bread - lab baked | 1.5 |
| 40 | Bread - lab baked | 1.9 |
| 41 | Bread - lab baked | 3.8 |
| 42 | Bread - lab baked | 3.0 |
| 43 | Bread - lab baked | 3.7 |

* 28 samples were deleted from the data base to correct for duplicate reporting of data (Jan. 20, 1984).

| GMA # | Product | ppb EDB |
|---|---|---|
| 44 | Bread - lab baked | 1.0 |
| 45 | Bread - lab baked | 1.1 |
| 46 | Bread - lab baked | (1 |
| 47 | Bread - lab baked | (1 |
| 48 | Bread - lab baked | (1 |
| 49 | Bread - lab baked | (1 |
| 50 | Bread - lab baked | (1 |
| 55 | Bread - lab baked | 3.0 |
| 56 | Bread - lab baked | 3.7 |
| 57 | Bread - lab baked | (1 |
| 58 | Bread - lab baked | (1 |
| 59 | Bread - lab baked | (1 |
| 64 | Bread - lab baked | (1 |
| 65 | Bread - lab baked | (1 |
| 66 | Bread - lab baked | (1 |
| 67 | Bread - lab baked | (1 |
| 68 | Bread - lab baked | (1 |
| 69 | Bread, pumpernickle - lab baked | (1 |
| 70 | Bread, pumpernickle - lab baked | (1 |
| 71 | Bread, pumpernickle - lab baked | (1 |
| 72 | Cake - commercial | (1 |
| 73 | Cake - lab baked | (1 |
| 74 | Cake - lab baked | (1 |
| 75 | Cake - lab baked | (1 |
| 76 | Cake - lab baked | (1 |
| 77 | Cake - lab baked | (1 |
| 78 | Cake - lab baked | 2.4 |
| 79 | Cake - lab baked | (2 |
| 80 | Cake - lab baked | (1 |
| 81 | Cake - lab baked | (1 |
| 82 | Cake - lab baked | 2 |
| 83 | Cake - lab baked | 11 |
| 84 | Cake - lab baked | 16 |
| 85 | Cake - lab baked | 4 |
| 86 | Cake - lab baked | (1 |
| 87 | Cake - lab baked | 4 |

| GMA # | Product | ppb EDB |
|---|---|---|
| 88 | Cake - lab baked | 8 |
| 89 | Cake - lab baked | (2 |
| 90 | Cake - lab baked | 2 |
| 91 | Cake - lab baked | (1 |
| 92 | Cake - lab baked | (1 |
| 93 | Cake - lab baked | (1 |
| 94 | Cake - lab baked | (1 |
| 95 | Cake - lab baked | 32 |
| 96 | Cake - lab baked | (1 |
| 97 | Cake - lab baked | (1 |
| 98 | Cake - lab baked | (1 |
| 99 | Cake - lab baked | (1 |
| 100 | Cake - yellow - lab baked | (1 |
| 101 | Cake - yellow - lab baked | (1 |
| 102 | Cake - yellow - lab baked | (1 |
| 103 | Cake - pound - lab baked | (1 |
| 104 | Cake - pound - lab baked | (1 |
| 105 | Cake - pound - lab baked | (1 |
| 106 | Cupcake - lab baked | (1 |
| 107 | Cake doughnuts-lab baked | (1 |
| 108 | Cake doughnuts-lab baked | (1 |
| 109 | Cake doughnuts-lab baked | (1 |
| 110 | Cereal-cold ready to eat | (1 |
| 111 | Cereal-cold ready to eat | (1 |
| 112 | Cereal-cold ready to eat | (1 |
| 113 | Cereal-cold ready to eat | (1 |
| 114 | Cereal-cold ready to eat | (1 |
| 115 | Cereal-cold ready to eat | (1 |
| 116 | Cereal-cold ready to eat | (1 |
| 117 | Cereal-cold ready to eat | (1 |
| 118 | Cereal-cold ready to eat | (1 |
| 119 | Cereal-cold ready to eat | (1 |
| 120 | Cereal-cold ready to eat | (1 |
| 121 | Cereal-cold ready to eat | (1 |
| 122 | Cookies | (1 |
| 123 | Cookies | (1 |
| 124 | Cookies | (1 |
| 125 | Cookies | (1 |
| 126 | Cookies | 15.5 |
| 127 | Cookies | 13.8 |
| 128 | Cookies | 11.9 |
| 129 | Cookies - Bordeaux | (1 |
| 130 | Cookies - irish oatmeal | (1 |
| 131 | Cookies - raisin bran | (1 |
| 132 | Cookies - lab baked | (1 |
| 133 | Cookies - Pies m-mellow | (1 |
| 134 | Cookies - granola | (1 |

| GMA # | Product | ppb EDB |
|---|---|---|
| 135 | Corn meal muffin | 17 |
| 136 | Corn meal muffin | (1 |
| 137 | Corn meal muffin | 1 |
| 138 | Corn meal muffin | (1 |
| 139 | Corn meal muffin | (1 |
| 140 | Corn meal muffin | 1.3 |
| 141 | Corn molasses bread | (1 |
| 142 | Corn muffin | 1.2 |
| 143 | Crackers | (1 |
| 144 | Crackers | (1 |
| 145 | Crackers | (1 |
| 146 | Crackers | (1 |
| 147 | Crackers | (1 |
| 148 | Crackers | (1 |
| 149 | Crackers | (1 |
| 150 | Grits - quick - cooked | (1 |
| 151 | Grits-boil-in-bag- cooked | (1 |
| 152 | Grits - quick - cooked | (1 |
| 153 | Grits - quick - cooked | (1 |
| 154 | Grits - quick - cooked | (1 |
| 155 | Grits - quick - cooked | (1 |
| 156 | Hush puppies - cooked | 2.5 |
| 157 | Hush puppies - cooked | 1.6 |
| 158 | Hush puppies - cooked | (1 |
| 159 | Hush puppies - cooked | (1 |
| 160 | Hush puppies - cooked | 1.2 |
| 161 | Milk | (1 |
| 162 | Milk | (1 |
| 163 | Muffins - bran rasin | (1 |
| 164 | Oatmeal - raisin | (1 |
| 165 | Orange Juice | (1 |
| 166 | Orange Juice | (1 |
| 167 | Pasta-Macaroni-cooked | 3.0 |
| 168 | Pasta-Macaroni-cooked | (1 |
| 169 | Pasta-Macaroni-cooked | 1.0 |
| 170 | Pasta-Macaroni-cooked | (1 |
| 171 | Pasta-Macaroni-cooked | (1 |
| 172 | Pasta-Macaroni-cooked | (1 |
| 173 | Pasta-cooked noodles | (1 |
| 174 | Pasta-cooked noodles | (1 |
| 175 | Pasta-cooked noodles | (1 |

| GMA # | Product | ppb EDB |
|---|---|---|
| 177 | Pasta-spagetti-cooked | (1 |
| 178 | Pasta-spagetti-cooked | (1 |
| 179 | Pasta-spagetti-cooked | (1 |
| 180 | Pineapple Juice | (1 |
| 181 | Pineapple Juice | (1 |
| 182 | potato rolls-baked | (1 |
| 183 | potato rolls baked | (1 |
| 184 | potato rolls baked | (1 |
| 185 | Wheat germ store pack | (1 |
| 186 | Wheat germ store pack | (1 |
| 187 | Wheat germ store pack | (1 |
| 188 | Wheat germ store pack | (1 |
| 189 | Wheat germ store pack | (1 |
| 190 | Wheat germ store pack | (1 |
| 191 | Wheat germ blend | (1 |
| 192 | Wheat germ blend | (1 |

( = less than
) = greated than

Table 7

## EDB LEVELS IN PRODUCTS
## Mixs, Meals, Flours, & Other Consumer Products Before Cooking

| GMA # | Product | ppb EDB |
|---|---|---|
| 193 | Bread mx - pumpernickle | 4.8 |
| 194 | Cake doughnut mix | (1 |
| 195 | Cake mix | (2 |
| 196 | Cake mix | 8 |
| 197 | Cake mix | 2 |
| 198 | Cake mix | 4 |
| 199 | Cake mix | 12 |
| 200 | Cake mix | 3 |
| 201 | Cake mix | 64 |
| 202 | Cake mix | 30 |
| 203 | Cake mix | 20 |
| 204 | Cake mix | (1 |
| 205 | Cake mix | (1 |
| 206 | Cake mix | 4 |
| 207 | Cake mix | 17 |
| 208 | Cake mix | 90 |
| 209 | Cake mix | 33 |
| 210 | Cake mix | (1 |
| 211 | Cake mix | (1 |
| 212 | Cake mix | 5.1 |
| 213 | Cake mix | 5.2 |
| 214 | Cake mix | 5.1 |
| 215 | Cake mix | (1 |
| 216 | Cake mix | (1 |
| 217 | Cake mix | (1 |
| 218 | Cake mix | (1 |
| 219 | Cake mix | (1 |
| 220 | Cake mix | (1 |
| 221 | Cake mix | (1 |
| 222 | Cake mix | (1 |
| 223 | Cake mix | 3 |
| 224 | Cake mix - yellow | (1 |
| 225 | Cake mix - pound | (1 |
| 226 | Cereal-to cook type-dry | 1.6 |
| 227 | Cereal-to cook type-dry | (1 |
| 228 | Cereal-to cook type-dry | 2.6 |
| 229 | Corn Meal | 17 |
| 230 | Corn Meal | 1.7 |
| 231 | Corn Meal | (1 |
| 232 | Corn Meal | (1 |
| 233 | Corn Meal | 500 |
| 234 | Corn Meal | 7.3 |

| GMA # | Product | ppb EDB |
|---|---|---|
| 235 | Corn Meal - Ground | 470 |
| 236 | Corn Meal-self rise | 380 |
| 237 | Corn Meal-self rise | 8.4 |
| 238 | Corn Meal-self rise | 7.3 |
| 239 | Corn Meal-self rise | 7.4 |
| 240 | Corn Meal-self rise | 6.4 |
| 241 | Corn Meal-self rise | 7.8 |
| 242 | Corn Meal-self rise | 4.8 |
| 243 | Corn Meal-self rise | 9.9 |
| 244 | Corn Meal-self rise | 3.9 |
| 245 | Corn Meal-self rise | 7.8 |
| 246 | Corn Meal-self rise | 11.0 |
| 247 | Corn Meal-self rise | 4.8 |
| 248 | Corn Meal-self rise | 6.4 |
| 249 | Corn Meal-self rise | 6.4 |
| 250 | Corn Meal-self rise | 3.2 |
| 251 | Corn Meal-self rise | 3.8 |
| 252 | Corn Meal-self rise | 7.8 |
| 253 | Corn Meal-self rise | 6.5 |
| 254 | Corn Meal-self rise | 4 |
| 255 | Corn Meal-self rise | 6.4 |
| 256 | Corn Meal-self rise | 7.6 |
| 257 | Corn Meal-self rise | 9 |
| 258 | Corn Meal-self rise | 12 |
| 259 | Corn Meal-self rise | 8 |
| 260 | Corn Meal-self rise | 4 |
| 261 | Corn Meal - White | 1.8 |
| 262 | Corn Meal - White | 1.5 |
| 263 | Corn Meal - White | 1.3 |
| 264 | Corn Meal - White | 990 |
| 265 | Corn Meal - White | 260 |
| 266 | Corn Meal - White | 50 |
| 267 | Corn Meal - White | 54 |
| 268 | Corn Meal - Yellow | 160 |
| 269 | Corn Meal - Yellow | 2.4 |
| 270 | Corn Meal - Yellow | 2.6 |
| 271 | Corn Meal - Yellow | 2.2 |
| 272 | Corn meal mix | 990.0 |
| 273 | Corn meal mix | 50.0 |
| 274 | Corn meal mix | 11.0 |
| 275 | Corn meal mix | 8.6 |
| 276 | Corn meal mix | 14.0 |
| 277 | Corn meal mix | 17.0 |
| 278 | Flour | 1.6 |
| 279 | Flour | 4.1 |
| 280 | Flour | 15 |
| 281 | Flour | 1.6 |

| GMA # | Product | ppb EDB |
|---|---|---|
| 282 | Flour | 1.3 |
| 283 | Flour | 1.2 |
| 284 | Flour | (1 |
| 285 | Flour | 1.3 |
| 286 | Flour | 4.1 |
| 287 | Flour | 1.9 |
| 288 | Flour | 2 |
| 289 | Flour | 37 |
| 290 | Flour | 27 |
| 291 | Flour | 1.9 |
| 292 | Flour | 1.1 |
| 293 | Flour | 1.9 |
| 294 | Flour | 30.3 |
| 295 | Flour | 2.7 |
| 296 | Flour | (1 |
| 297 | Flour | (1 |
| 298 | Flour | 3.7 |
| 299 | Flour | (1 |
| 300 | Flour | 1 |
| 301 | Flour | 2.8 |
| 302 | Flour | 13.4 |
| 303 | Flour | 1.3 |
| 304 | Flour | 5 |
| 305 | Flour | 2.1 |
| 306 | Flour | 164 |
| 307 | Flour | 3 |
| 308 | Flour | 11.9 |
| 309 | Flour | 5.8 |
| 310 | Flour | 2.2 |
| 311 | Flour | 4.8 |
| 312 | Flour | 5.3 |
| 313 | Flour | 4.5 |
| 314 | Flour | 7.9 |
| 315 | Flour | 3.9 |
| 316 | Flour | (1 |
| 317 | Flour | 5.7 |
| 318 | Flour | 3.3 |
| 319 | Flour | 3.8 |
| 320 | Flour | 2.4 |
| 321 | Flour | (1 |
| 322 | Flour | 1.8 |
| 323 | Flour | 4.4 |
| 324 | Flour | 3.7 |
| 325 | Flour | 1 |
| 326 | Flour | 1.7 |
| 327 | Flour | 2.6 |
| 328 | Flour | 1.7 |
| 329 | Flour | 55 |

| GMA # | Product | ppb EDB |
|---|---|---|
| 330 | Flour | 5 |
| 335 | Flour | 2.8 |
| 336 | Flour | 1 |
| 337 | Flour | (1 |
| 338 | Flour | 1.5 |
| 339 | Flour | 13 |
| 340 | Flour | 5 |
| 341 | Flour | (4 |
| 342 | Flour | (1 |
| 343 | Flour | (1 |
| 344 | Flour | (4 |
| 345 | Flour | 2 |
| 346 | Flour | (4 |
| 347 | Flour | (4 |
| 348 | Flour | (4 |
| 349 | Flour | 11 |
| 350 | Flour | (2 |
| 351 | Flour | 450 |
| 352 | Flour | 31 |
| 353 | Flour | 19 |
| 354 | Flour | 10 |
| 355 | Flour | 9 |
| 356 | Flour | 54 |
| 357 | Flour | 82 |
| 358 | Flour | 6 |
| 359 | Flour | 9 |
| 360 | Flour | 7 |
| 361 | Flour | 4 |
| 362 | Flour | 6 |
| 363 | Flour | 18 |
| 364 | Flour | 36 |
| 365 | Flour | 2 |
| 366 | Flour | 100 |
| 367 | Flour | 6 |
| 368 | Flour | 9 |
| 369 | Flour | 5 |
| 370 | Flour | 1 |
| 371 | Flour | 4 |
| 372 | Flour | 1 |
| 373 | Flour | 2 |
| 374 | Flour | 3.8 |
| 375 | Flour | 5.8 |
| 376 | Flour | 6.1 |
| 377 | Flour | 2.4 |

| GMA # | Product | ppb EDB |
|---|---|---|
| 378 | Flour | 5 |
| 379 | Flour | ) 100 |
| 380 | Flour | 2 |
| 381 | Flour | (1 |
| 382 | Flour | 2 |
| 383 | Flour | 6 |
| 384 | Flour | 14 |
| 385 | Flour | 6 |
| 386 | Flour | 3 |
| 387 | Flour | 4 |
| 388 | Flour | ) 100 |
| 389 | Flour | 5 |
| 390 | Flour | ) 100 |
| 391 | Flour | 11 |
| 392 | Flour | 37 |
| 393 | Flour | 88 |
| 394 | Flour | 123 |
| 395 | Flour | 280 |
| 396 | Flour | 120 |
| 397 | Flour | 61 |
| 398 | Flour | 91 |
| 399 | Flour | 170 |
| 400 | Flour | (4 |
| 401 | Flour | 33 |
| 402 | Flour | 3 |
| 403 | Flour | (4 |
| 404 | Flour | (4 |
| 405 | Flour | (4 |
| 406 | Flour | 1 |
| 407 | Flour | 1 |
| 408 | Flour | (4 |
| 409 | Flour | (4 |
| 410 | Flour | (1 |
| 411 | Flour | (4 |
| 412 | Flour | 64 |
| 413 | Flour | 28 |
| 414 | Flour | ) 100 |
| 415 | Flour | ) 100 |
| 416 | Flour | ) 100 |
| 417 | Flour | ) 100 |
| 418 | Flour | ) 100 |
| 419 | Flour | ) 100 |
| 420 | Flour | 4 |
| 421 | Flour | 4 |
| 422 | Flour | 9 |
| 423 | Flour | 3 |
| 424 | Flour | 18 |
| 425 | Flour | 11 |

| GMA # | Product | ppb EDB |
|---|---|---|
| 426 | Flour | 4 |
| 427 | Flour | ) 100 |
| 428 | Flour | 80 |
| 429 | Flour | 5 |
| 430 | Flour | (1 |
| 431 | Flour | (1 |
| 432 | Flour | 1 |
| 433 | Flour | 146 |
| 434 | Flour | 31 |
| 435 | Flour | 40 |
| 436 | Flour | 51 |
| 437 | Flour | 10 |
| 438 | Flour | 11.4 |
| 439 | Flour | 8.0 |
| 440 | Flour | 17.7 |
| 441 | Flour | 2.0 |
| 442 | Flour | 7.5 |
| 443 | Flour | 21.1 |
| 444 | Flour | 2.4 |
| 445 | Flour | 29.9 |
| 446 | Flour | 2.6 |
| 447 | Flour | 6.2 |
| 448 | Flour | 1.3 |
| 449 | Flour | 13.0 |
| 450 | Flour | 8.3 |
| 451 | Flour | 3.7 |
| 452 | Flour | 10.8 |
| 453 | Flour | 2.8 |
| 454 | Flour | 1.9 |
| 455 | Flour | 1.9 |
| 456 | Flour | 1.9 |
| 457 | Flour | 11.6 |
| 458 | Flour | 16.7 |
| 459 | Flour | 1.3 |
| 460 | Flour | (1 |
| 461 | Flour | 5.1 |
| 462 | Flour | 9.9 |
| 463 | Flour | (1 |
| 464 | Flour | (1 |
| 465 | Flour | (1 |
| 466 | Flour | (1 |
| 467 | Flour | (1 |
| 468 | Flour | 21.1 |
| 469 | Flour | 7.5 |
| 470 | Flour | (1 |
| 471 | Flour | 6.2 |
| 472 | Flour | 13.5 |
| 474 | Flour | 4.2 |

| GMA # | Product | ppb EDB |
|---|---|---|
| 475 | Flour | 4.6 |
| 479 | Flour | (1 |
| 480 | Flour | (1 |
| 481 | Flour | (1 |
| 482 | Flour | (1 |
| 483 | Flour (retail) | (1 |
| 484 | Flour (retail) | (1 |
| 485 | Flour (retail) | 11 |
| 486 | Flour (retail) | (1 |
| 487 | Flour (retail) | (1 |
| 488 | Flour (retail) | (1 |
| 489 | Flour (retail) | (1 |
| 490 | Flour (retail) | (1 |
| 491 | Flour (retail) | 2 |
| 492 | Flour (retail) | 3 |
| 493 | Flour (retail) | 3 |
| 494 | Flour (retail) | 2 |
| 495 | Flour (retail) | (1 |
| 496 | Flour (retail) | (1 |
| 497 | Flour (retail) | (1 |
| 498 | Flour - cracked wheat | 14.6 |
| 499 | Flour - hard red wheat | (1 |
| 500 | Flour - hard red wheat | (1 |
| 501 | Flour - hard red wheat | (1 |
| 506 | Flour - industrial | 4.3 |
| 507 | Flour - industrial | 8.3 |
| 509 | Flour - industrial | 7.2 |
| 510 | Flour - industrial | 30.4 |
| 511 | Flour - industrial | 24.1 |
| 513 | Flour - industrial | 19.4 |
| 514 | Flour - industrial | 13.8 |
| 515 | Flour - consumer pack | 1.0 |
| 516 | Flour - consumer pack | 1.0 |
| 517 | Flour - low grade | 5.2 |
| 518 | Flour - low grade | 8.5 |
| 519 | Flour - low grade | 3.0 |
| 520 | Flour - low grade | 18.2 |
| 521 | Flour - low grade | 7.1 |
| 522 | Flour - low grade | 11.7 |

| GMA # | Product | ppb EDB |
|---|---|---|
| 523 | Flour - low grade | 18.9 |
| 524 | Flour - low grade | 7.3 |
| 525 | Flour - low grade | 14.7 |
| 526 | Flour - low grade | 17.2 |
| 527 | Flour - low grade | 9.4 |
| 528 | Flour - low grade | 36.7 |
| 529 | Flour - low grade | 17.2 |
| 530 | Flour - low grade | 9.4 |
| 531 | Flour - low grade | 36.7 |
| 532 | Flour - low grade | 261 |
| 533 | Flour - low grade | 291 |
| 534 | Flour - low grade | 428 |
| 535 | Flour - low grade | 435 |
| 536 | Flour - low grade | 39.8 |
| 537 | Flour - low grade | 3.4 |
| 538 | Flour - low grade | 39.5 |
| 539 | Flour, Self Rising | 1.8 |
| 540 | Flour, Self Rising | 1.8 |
| 541 | Flour, Self Rising | 1 |
| 542 | Flour, Self Rising | 2.7 |
| 543 | Flour - whole wheat | 5 |
| 544 | Flour - wheat | 2.4 |
| 545 | Flour - whole wheat | 2.9 |
| 546 | Grits-Quick | (1 |
| 547 | Grits-Quick | (1 |
| 548 | Grits-Quick | (1 |
| 549 | Grits-Quick | (1 |
| 550 | Grits-Quick | (1 |
| 551 | Grits-Quick | (1 |
| 552 | Grits-Quick | 1.3 |
| 553 | Grits-Quick | 1.8 |
| 554 | Grits-Quick | 1 |
| 555 | Grits-Quick | 1 |
| 556 | Grits-Quick | 2.2 |
| 557 | Grits-Quick | 1.3 |
| 558 | Grits-Quick | 5.9 |
| 559 | Grits-Quick | 12.0 |
| 560 | Grits-Quick | 15.0 |
| 561 | Grits-Quick | 8.8 |
| 562 | Grits-Quick | 8.3 |
| 563 | Hush Puppy Mix | 860 |
| 564 | Hush Puppy Mix | 423 |
| 565 | Hush Puppy Mix | 157 |
| 566 | Hush Puppy Mix | 520 |
| 567 | Hush Puppy Mix | 681 |
| 568 | Hush Puppy Mix | 72 |

| GMA # | Product | ppb EDB |
|---|---|---|
| 569 | Hush Puppy Mix | 211 |
| 570 | Hush Puppy Mix | 242 |
| 571 | Hush Puppy Mix | 527 |
| 572 | Hush Puppy Mix | 227 |
| 573 | Hush Puppy Mix | 423 |
| 574 | Hush Puppy Mix | 534 |
| 575 | Hush Puppy Mix | 638 |
| 576 | Hush Puppy Mix | 595 |
| 577 | Hush puppy mix/onions | 20.0 |
| 578 | Multi grain mix | (1 |
| 579 | Multi grain mix | 3.8 |
| 580 | Oats, Instant Rolled | (1 |
| 581 | Oats, Instant Rolled | (1 |
| 582 | Oats, Instant Rolled | (1 |
| 583 | Oats, Instant Rolled | (1 |
| 584 | Oats - Irish | (1 |
| 585 | Oats Rolled | (1 |
| 586 | Oats Rolled | (1 |
| 587 | Oats Rolled | (1 |
| 588 | Oats, Quick Rolled | (1 |
| 589 | Oats, Quick Rolled | (1 |
| 590 | Oats, Quick Rolled | (1 |
| 591 | Oats - rolled | 1.8 |
| 592 | Oats - rolled | (1 |
| 593 | Pancake Mix | 1.2 |
| 594 | Pancake Mix | (1 |
| 595 | Pancake Mix | 1.7 |
| 596 | Pasta-Egg Noodle/dry | (1 |
| 597 | Pasta-Egg Noodle/dry | (1 |
| 598 | Pasta-Egg Noodle/dry | (1 |
| 599 | Pasta-Egg Noodle/dry | (1 |
| 600 | Pasta-Egg Noodle/dry | 2.1 |
| 601 | Pasta-Egg Noodle/dry | 2.2 |
| 602 | Pasta-Egg Noodle/dry | 7.6 |
| 603 | Pasta-Egg Noodle/dry | 2.7 |
| 604 | Pasta-Egg Noodle/dry | (1 |
| 605 | Pasta-Macaroni-uncooked | 7. |
| 606 | Pasta-Macaroni-uncooked | 2 |
| 607 | Pasta-Macaroni-uncooked | 2.3 |
| 608 | Pasta-Macaroni-uncooked | 13.3 |
| 609 | Pasta-Macaroni-uncooked | 2.1 |
| 610 | Pasta-Macaroni-uncooked | (1 |
| 611 | Pasta-Macaroni-uncooked | 8.1 |
| 612 | Pasta-Macaroni-uncooked | 5.2 |

| GMA # | Product | ppb EDB |
|---|---|---|
| 613 | Pasta-Macaroni-uncooked | 12.6 |
| 614 | Pasta-Macaroni-uncooked | 2.7 |
| 615 | Pasta-Macaroni-uncooked | 9.4 |
| 616 | Pasta-Macaroni-uncooked | 4.2 |
| 617 | Pasta-Macaroni-uncooked | 6.9 |
| 618 | Pasta-Macaroni-uncooked | 17.1 |
| 619 | Pasta-Macaroni-uncooked | 1.8 |
| 620 | Pasta-Macaroni-uncooked | 1.5 |
| 621 | Pasta-Macaroni-uncooked | (1 |
| 622 | Pasta-Macaroni-uncooked | 1.0 |
| 623 | Pasta-Macaroni-uncooked | (1 |
| 624 | Pasta-Macaroni-uncooked | 1.2 |
| 625 | Pasta-Macaroni-uncooked | (1 |
| 626 | Pasta-Macaroni-uncooked | 1.0 |
| 627 | Pasta-Macaroni-uncooked | (1 |
| 628 | Pasta-Macaroni-uncooked | (1 |
| 629 | Pasta-Macaroni-uncooked | (1 |
| 630 | Pasta-Macaroni-uncooked | (1 |
| 631 | Pasta-Macaroni-uncooked | (1 |
| 632 | Pasta-Macaroni-uncooked | (1 |
| 633 | Pasta-Macaroni-uncooked | (1 |
| 634 | Pasta-Macaroni-uncooked | (1 |
| 635 | Pasta-Macaroni-uncooked | 8.2 |
| 636 | Pasta-Macaroni-uncooked | 2.4 |
| 637 | Pasta-Macaroni-uncooked | 1.2 |
| 638 | Pasta-Macaroni-uncooked | (1 |
| 639 | Pasta-Macaroni-uncooked | (1 |
| 640 | Pasta-Macaroni-uncooked | (1 |
| 641 | Pasta-Macaroni-uncooked | 1.0 |
| 642 | Pasta-Macaroni-uncooked | (1 |
| 643 | Pasta uncooked noodle | (1 |
| 644 | Pasta uncooked noodle | (1 |
| 645 | Pasta uncooked noodle | (1 |
| 646 | Pasta uncooked noodle | (1 |
| 647 | Pasta uncooked noodle | (1 |
| 648 | Pasta uncooked noodle | 2 |
| 649 | Pasta uncooked noodle | 3 |
| 650 | Pasta uncooked noodle | (1 |
| 651 | Pasta uncooked noodle | 1.3 |
| 652 | Pasta uncooked noodle | (1 |
| 653 | Pasta uncooked noodle | 1.9 |
| 654 | Pasta uncooked noodle | 1.4 |
| 655 | Pasta uncooked noodle | (1 |
| 656 | Pasta uncooked noodle | (1 |
| 657 | Pasta uncooked noodle | (1 |
| 658 | Pasta uncooked noodle | (1 |
| 659 | Pasta uncooked noodle | 1.0 |

| GMA # | Product | ppb EDB |
|---|---|---|
| 660 | Pasta uncooked noodle | (1 |
| 661 | Pasta uncooked noodle | (1 |
| 662 | Pasta uncooked noodle | 1.1 |
| 663 | Pasta uncooked noodle | (1 |
| 664 | Pasta uncooked noodle | 16.0 |
| 665 | Pasta uncooked noodle | 8.5 |
| 666 | Pasta uncooked noodle | 1.0 |
| 667 | Pasta uncooked noodle | 3.5 |
| 668 | Pasta uncooked noodle | 1.0 |
| 669 | Pasta uncooked noodle | 5.6 |
| 670 | Pasta uncooked noodle | 1.1 |
| 671 | Pasta uncooked noodle | 2.1 |
| 672 | Pasta uncooked noodle | 2.8 |
| 673 | Pasta uncooked noodle | (1 |
| 674 | Pasta uncooked noodle | (1 |
| 675 | Pasta uncooked noodle | (1 |
| 676 | Pasta uncooked noodle | (1 |
| 677 | Pasta uncooked noodle | (1 |
| 678 | Pasta uncooked noodle | (1 |
| 679 | Pasta-shells uncooked | 1.6 |
| 680 | Pasta-uncooked spagetti | (1 |
| 681 | Pasta-uncooked spagetti | 15.9 |
| 682 | Pasta-uncooked spagetti | 11.0 |
| 683 | Pasta-uncooked spagetti | 1.3 |
| 684 | Pasta-uncooked spagetti | (1 |
| 685 | Pasta-uncooked spagetti | (1 |
| 686 | Pasta-uncooked spagetti | (1 |
| 687 | Pasta-uncooked spagetti | (1 |
| 688 | Pasta-uncooked spagetti | (1 |
| 689 | Pasta-uncooked spagetti | (1 |
| 690 | Pasta-uncooked spagetti | (1 |
| 691 | Pasta-uncooked spagetti | 4.3 |
| 692 | Pasta-uncooked spagetti | 1.0 |
| 693 | Pasta-uncooked spagetti | 1.1 |
| 694 | Pasta-uncooked spagetti | (1 |
| 695 | Pasta-uncooked spagetti | (1 |
| 696 | Pasta-uncooked spagetti | (1 |
| 697 | Pasta-uncooked spagetti | 1.2 |
| 698 | Pasta-uncooked spagetti | (1 |
| 699 | Pasta-uncooked spagetti | (1 |
| 700 | Pasta-uncooked spagetti | (1 |
| 701 | Pasta-uncooked spagetti | 17.4 |
| 702 | Pasta-uncooked spagetti | (1 |
| 703 | Pasta-uncooked spagetti | (1 |
| 704 | Pasta-uncooked spagetti | (1 |
| 705 | Pasta-uncooked spagetti | (1 |
| 706 | Pasta-uncooked spagetti | 7.7 |

| GMA # | Product | ppb EDB |
|---|---|---|
| 707 | Pasta-uncooked spagetti | (1 |
| 708 | Pasta-uncooked spagetti | (1 |
| 709 | Pasta-uncooked spagetti | (1 |
| 710 | Pasta-uncooked spagetti | (1 |
| 711 | Pasta-uncooked spagetti | (1 |
| 712 | Pasta-uncooked spagetti | (1 |
| 713 | Pasta-uncooked spagetti | (1 |
| 714 | Pasta-uncooked spagetti | 1.7 |
| 715 | Pasta-uncooked spagetti | 1.4 |
| 716 | Pasta-uncooked spagetti | 1.1 |
| 717 | Pasta-uncooked spagetti | 4 |
| 718 | Pasta-uncooked spagetti | (1 |
| 719 | Pasta-uncooked spagetti | (1 |
| 720 | Pasta-uncooked spagetti | (1 |
| 721 | Pasta-uncooked spagetti | (1 |
| 722 | Pasta-uncooked spagetti | (1 |
| 723 | Pasta-uncooked spagetti | (1 |
| 724 | Pasta-uncooked spagetti | (1 |
| 725 | Pasta-uncooked spagetti | (1 |
| 726 | Pasta-uncooked spagetti | (1 |
| 727 | Pasta-uncooked spagetti | (1 |
| 728 | Pasta-uncooked spagetti | (1 |
| 729 | Pasta-uncooked spagetti | (1 |
| 730 | Pasta-uncooked spagetti | (1 |
| 731 | Pasta-uncooked spagetti | (1 |
| 732 | Pasta-uncooked spagetti | (1 |
| 733 | Pasta-uncooked spagetti | (1 |
| 734 | Pasta-uncooked spagetti | (1 |
| 735 | Pasta-uncooked spagetti | (1 |
| 736 | Pasta-uncooked spagetti | (1 |
| 737 | Potato roll mix | 5.15 |
| 738 | Pizza Dry Mix | 2.7 |
| 739 | Red dog (a wheat by-product) | 38.0 |
| 740 | Semolina (a flour fraction for pasta) | 2 |
| 741 | Semolina | 9.2 |
| 742 | Semolina | (1 |
| 743 | Semolina | (1 |
| 744 | Semolina | (1 |
| 745 | Semolina | 1.3 |
| 746 | Wheat Gluten | 1.1 |

( = less than
) = greated than

Table 8

EDB LEVELS IN GRAINS AND GRAIN BY PRODUCTS

| GMA # | Product | ppb EDB |
|---|---|---|
| 747 | Corn | 874 |
| 748 | Corn | 188 |
| 749 | Corn | 538 |
| 750 | Corn | 5 |
| 751 | Corn | 18 |
| 752 | Corn | 2.8 |
| 753 | Corn | 8 |
| 754 | Corn | (1 |
| 755 | Corn | 16.2 |
| 756 | Corn | 14.3 |
| 757 | Corn | 19.8 |
| 758 | Corn | (1 |
| 759 | Corn | 1.8 |
| 760 | Corn | 92 |
| 761 | Corn | 11 |
| 762 | Corn | 423 |
| 763 | Corn | 435 |
| 764 | Corn | 347 |
| 765 | Corn | 26,600 |
| 766 | Corn | 413 |
| 767 | Corn | 970 |
| 768 | Corn | 34 |
| 769 | Corn | 29 |
| 770 | Corn | 59 |
| 771 | Corn | 272 |
| 772 | Corn | 29 |
| 773 | Corn | 18 |
| 774 | Corn | 1.3 |
| 775 | Corn | (1 |
| 776 | Corn, White | 63.6 |
| 777 | Corn, White | (1 |
| 778 | Corn, White | (1 |
| 779 | Corn, White | (1 |
| 780 | Corn, White | (1 |
| 781 | Corn, White | (1 |
| 782 | Corn, White | (1 |
| 783 | Corn, White | (1 |
| 784 | Corn, White | (1 |
| 785 | Corn, White | (1 |
| 786 | Corn, White | (1 |
| 787 | Corn, White | (1 |
| 788 | Corn, White | (1 |
| 789 | Corn, White | (1 |

| GMA # | Product | ppb EDB |
|---|---|---|
| 790 | Corn, White | (1 |
| 791 | Corn, White | 2.4 |
| 792 | Corn, White | 1 |
| 793 | Corn, White | 4.3 |
| 794 | Corn, White | 1.5 |
| 795 | Corn, White | 1 |
| 796 | Corn, White | 1 |
| 797 | Corn, Yellow | 85.2 |
| 798 | Corn, Yellow | (1 |
| 799 | Corn, Yellow | (1 |
| 800 | Corn, Yellow | (1 |
| 801 | Corn, Yellow | (1 |
| 802 | Corn, Yellow | (1 |
| 803 | Corn, Yellow | (1 |
| 804 | Corn, Yellow | (1 |
| 805 | Corn, Yellow | (1 |
| 806 | Corn, Yellow | 1.6 |
| 807 | Corn, Yellow | (1 |
| 808 | Midds (a wheat | 5.0 |
| 809 | Midds by product) | 19.4 |
| 810 | Midds | 7.4 |
| 811 | Midds | 28.4 |
| 812 | Midds | 19.6 |
| 813 | Midds | 148.0 |
| 814 | Midds | 9.1 |
| 815 | Midds | 23.8 |
| 816 | Midds | 121.0 |
| 817 | Midds | 55.0 |
| 818 | Midds | 6.0 |
| 819 | Midds | 47.9 |
| 820 | Midds | 22.5 |
| 821 | Midds | 2.8 |
| 822 | Midds | 3.3 |
| 823 | Oats | (1 |
| 824 | Oats | (1 |
| 825 | Oats | (1 |
| 826 | Oats | 1.8 |
| 827 | Oats | 152 |
| 828 | Oats | 18 |
| 829 | Oats | 22.4 |
| 830 | Oats | 20.1 |
| 831 | Oats | 3.6 |

| GMA # | Product | ppb EDB |
|---|---|---|
| 832 | Oats | 26.9 |
| 833 | Oats | 3.9 |
| 834 | Oats | 1.7 |
| 835 | Oats | (1 |
| 836 | Rice | (1 |
| 837 | Rice | (1 |
| 838 | Rice | (1 |
| 839 | Rice | (1 |
| 840 | Rice | (1 |
| 841 | Rice | 2.2 |
| 842 | Rice | 2.4 |
| 843 | Rice | (1 |
| 844 | Rice | (1 |
| 845 | Rice | (1 |
| 846 | Rice | (1 |
| 847 | Rice | (1 |
| 848 | Rice | (1 |
| 849 | Rice | (1 |
| 850 | Rice - brown | (1 |
| 851 | Rice - brown | (1 |
| 852 | Rice - Enriched | (1 |
| 853 | Rice - Enriched | (1 |
| 854 | Rice - Enriched | (1 |
| 855 | Rice - Enriched | (1 |
| 856 | Rice - Enriched | (1 |
| 857 | Rice - Enriched | (1 |
| 858 | Rice - Long Grain | (1 |
| 859 | Rice - Long Grain | (1 |
| 860 | Rice - Long Grain | (1 |
| 861 | Rice - Long Grain | 1.1 |
| 862 | Rice - Long Grain | (1 |
| 863 | Rice - Long Grain | (1 |
| 864 | Rice - Long Grain | (1 |
| 865 | Rice - Long Grain | (1 |
| 866 | Rice - Long Grain | (1 |
| 867 | Rice - Long Grain | (1 |
| 868 | Rice - Long Grain | (1 |
| 869 | Rice - Long Grain-Enr | (1 |
| 870 | Rice - Long Grain-Enr | 7.7 |
| 871 | Rice - Long Grain-Enr | (1 |
| 872 | Rice - Long Grain-Enr | (1 |
| 873 | Rice - Long Grain-Enr | (1 |
| 874 | Rice - Long Grain-Enr | (1 |
| 875 | Rice - Long Grain-Enr | (1 |
| 876 | Rice - Long Grain-Enr | (1 |
| 877 | Rice - milled | (1 |
| 878 | Rice - milled | (1 |

| GMA # | Product | ppb EDB |
|---|---|---|
| 879 | Rice - milled | (1 |
| 880 | Rice - milled | (1 |
| 881 | Rice - milled | (1 |
| 882 | Rice - milled | (1 |
| 883 | Rice - Rough Paddy | (1 |
| 884 | Rice - Rough Paddy | (1 |
| 885 | Rice - Rough Paddy | (1 |
| 886 | Rice - Rough Paddy | (1 |
| 887 | Rice - Rough Paddy | (1 |
| 888 | Rice - Rough Paddy | (1 |
| 889 | Rice - Rough Paddy | (1 |
| 890 | Rice - Rough Paddy | (1 |
| 891 | Rice - Rough Paddy | (1 |
| 892 | Rice - Rough Paddy | 4.0 |
| 893 | Shorts ( a wheat by-product) | 31.5 |
| 894 | Wheat | (1 |
| 895 | Wheat | 5 |
| 896 | Wheat | (1 |
| 897 | Wheat | (1 |
| 898 | Wheat | 21.8 |
| 899 | Wheat | 1.7 |
| 900 | Wheat | 14.6 |
| 901 | Wheat | 21.9 |
| 902 | Wheat | 6.2 |
| 903 | Wheat | 6.6 |
| 904 | Wheat | (1 |
| 905 | Wheat | 5.8 |
| 906 | Wheat | 5.6 |
| 907 | Wheat | 41.7 |
| 908 | Wheat | 13.1 |
| 909 | Wheat | (1 |
| 910 | Wheat | (1 |
| 911 | Wheat | (1 |
| 912 | Wheat | 11.9 |
| 913 | Wheat | 1.6 |
| 914 | Wheat | (1 |
| 915 | Wheat | 21 |
| 916 | Wheat | 1.7 |
| 917 | Wheat | 4.8 |
| 918 | Wheat | (1 |
| 919 | Wheat | 1.2 |
| 920 | Wheat | (1 |

| GMA # | Product | ppb EDB |
|---|---|---|
| 921 | Wheat | 21.8 |
| 922 | Wheat | 1.0 |
| 923 | Wheat | 5.2 |
| 924 | Wheat | 1.5 |
| 925 | Wheat | (1 |
| 926 | Wheat | (1 |
| 927 | Wheat | (1 |
| 928 | Wheat | 4.6 |
| 929 | Wheat | 19.5 |
| 930 | Wheat | (1 |
| 931 | Wheat | 20.2 |
| 932 | Wheat | 61.0 |
| 933 | Wheat | 30.0 |
| 934 | Wheat | 5.6 |
| 935 | Wheat | 13.6 |
| 936 | Wheat | 70.5 |
| 937 | Wheat - Soft | 650 |
| 938 | Wheat | 34.8 |
| 939 | Wheat | 4.6 |
| 940 | Wheat | 26.2 |
| 941 | Wheat | (1 |
| 942 | Wheat | (1 |
| 943 | Wheat | (1 |
| 944 | Wheat | (1 |
| 945 | Wheat | (1 |
| 946 | Wheat | (1 |
| 947 | Wheat | 3 |
| 948 | Wheat | 23 |
| 949 | Wheat | 25 |
| 950 | Wheat | 45 |
| 951 | Wheat | (1 |
| 952 | Wheat | (1 |
| 953 | Wheat | (1 |
| 954 | Wheat | (1 |
| 955 | Wheat | (1 |
| 956 | Wheat | (1 |
| 957 | Wheat | 3 |
| 958 | Wheat | 4 |
| 959 | Wheat | (1 |
| 960 | Wheat | (1 |
| 961 | Wheat | 6 |
| 962 | Wheat kernels | 1.0 |
| 963 | Wheat, Durun | (1 |

| GMA # | Product | ppb EDB |
|---|---|---|
| 964 | Wheat, Durum | (1 |
| 965 | Wheat, Durum | (1 |
| 966 | Wheat, Durum | 1.6 |
| 967 | Wheat, Durum mix | 12.0 |
| 968 | Wheat, Hard Spring | 2.3 |
| 969 | Wheat, Hard Spring | 2.1 |
| 970 | Wheat - red | 8.3 |
| 971 | Wheat - red | 7.8 |
| 972 | Wheat - red | 1.7 |
| 973 | Wheat - red | 1.1 |
| 974 | Wheat - red | 50.5 |
| 975 | Wheat - red | (1 |
| 976 | Wheat - red | (1 |
| 977 | Wheat - red | (1 |
| 978 | Wheat - red | (1 |
| 979 | Wheat - red | (1 |
| 980 | Wheat-red winter, hard | (1 |
| 981 | Wheat-red winter, hard | (1 |
| 982 | Wheat-red winter, hard | (1 |
| 983 | Wheat-red winter, hard | (1 |
| 984 | Wheat-red winter, hard | (1 |
| 985 | Wheat - spring | 5.8 |
| 986 | Wheat - spring | 2.7 |
| 987 | Wheat - spring | (1 |
| 988 | Wheat - spring | (1 |
| 989 | Wheat - spring | (1 |
| 990 | Wheat - winter | (1 |
| 991 | Wheat - winter | (1 |
| 992 | Wheat - winter | 1.4 |
| 993 | Wheat - winter | 2.1 |
| 994 | Wheat - winter | (1 |
| 995 | Wheat - winter blend | 1.7 |
| 996 | Wheat bran - hard | 17.4 |
| 997 | Wheat bran | (1 |
| 998 | Wheat bran | (1 |
| 999 | Wheat bran | (1 |
| 1000 | Wheat bran | 3.8 |
| 1001 | Wheat bran | 7.3 |
| 1002 | Wheat bran - soft | 2.4 |
| 1003 | Wheat germ | 1.4 |
| 1004 | Wheat germ-hard-raw | 29.5 |
| 1005 | Wheat germ-hard-raw | 29.9 |
| 1006 | Wheat germ-hard-raw | 27.8 |
| 1007 | Wheat germ-soft-raw | 3.6 |
| 1008 | Wheat germ-soft-raw | 1.6 |
| 1009 | Wheat germ-soft-raw | 1.0 |
| 1010 | Wheat germ-soft-raw | (1 |

( = less than
) = greated than

## STATEMENT OF DR. SEYMOUR L. FRIESS, TOXICOLOGICAL CONSULTANTS, ARLINGTON, VA.

My name is Dr. Seymour L. Friess. I am the president of a firm of consulting toxicologists based in Arlington, Virginia. My personal credentials include extensive research in toxicology, pharmacology and chemistry, and safety evaluation for important chemicals impacting on human populations and the environment. I am a past-president of the (U.S.) Society of Toxicology, of the American Board of Toxicology, Inc., and of the international scientific union in this discipline, the International Union of Toxicology.

Beginning in late 1980, my firm of consultants was retained by the Florida Citrus Commission and other interested organizations to conduct studies of the scientific research literature on potential health effects of the important agricultural chemical ethylene dibromide (EDB), both in experimental animal species and in human populations exposed occupationally or through the food chain. From our review of the toxicological and epidemiological literature on EDB, plus the increasing body of available data on human exposure situations, my colleagues and I have reached certain conclusions about the ability of this chemical to evoke specific health effects in test animals or humans as a function of the exposures (or dosages) encountered, the duration of exposures, and the route by which the exposure occurs, e.g. by oral ingestion in foods or water, by inhalation, etc. Today, I would like to comment briefly on these health effect observations, and their significance in respect to risk assessment in the human for a major, life-threatening effect such as cancer.

The toxicological research literature reveals that a major health effect produced in test animals by dosing for large fractions of a lifetime, at high dosages, by either oral ingestion or by inhalation of EDB, is chemically-induced cancer. There are two major chronic studies which demonstrate this effect in rats and mice, both carried out under the auspices of the National

Cancer Institute in the late 1970s, and designated as chronic bioassays. Additionally, there is literature evidence for mutagenic potential of EDB in various types of mutagenicity tests, and for effects at high dosage levels on the production and structure of sperm and on male reproductive organs in such mammalian species as the bull, mouse, and rat.

There are at least three studies of potential health effects in human populations exposed occupationally to EDB over long periods of time, with high inhalation exposures experienced in the course of manufacture, blending, packaging, etc. These studies were focused on the major effect of concern, cancer, and analyzed in terms of any excess incidence rates of cancer in EDB-exposed workers beyond the rates to be expected in control populations. Although these studies do have flaws, in common with most epidemiological studies, they are essentially negative for excess cancer in exposed workers.

Despite the negative epidemiological results, the finding of carcinogenic potency of EDB in test rodents by two different routes of exposure has led to a generally accepted designation of EDB as a chemical carcinogen in animals, at the dosages employed. The regulatory community in the U.S. has therefore adopted the stance that the chemical is a potential human carcinogen, even if the cancer effect has not been seen in the most heavily exposed human populations, and that risk assessment for this potential effect in humans should be carried out by combining the cancer incidence rates from the appropriate bioassay data in test rats with either actual or theoretical exposures of human populations.

For risk assessment modelled on repetitive human exposures via eating or drinking of trace amounts of EDB in grains or grain products, citrus fruit, drinking water, etc, the mode of exposure in the animal bioassay should approximate as closely as possible the human mode of exposure. It is unfortunate that there is only one EDB bioassay which even approaches the human mode of exposure by oral ingestion, and that is the National Cancer Institute bioassay of 1978 in which the chemical was delivered on a daily basis directly to the forestomach of the rat or mouse, as a single dosage dissolved in corn oil, by a tube inserted through the mouth of the animal and extending directly down to the forestomach. This exposure mode is a very poor surrogate for normal exposures via eating and drinking, and resulted in a bioassay that was very seriously flawed in many respects. We hold that these flaws, especially as they led to an inability to generate a reliable dosage vs. response relationship for cancer in the target organ, rendered this experiment unusable for any process of cancer risk assessment directed to exposed humans.

The major flaws in this bioassay include the following. (1) Dose selection was extremely poor, resulting in so much early death in the test animal population that the experiment was terminated at about one-half the design interval, wiping out the intended use of results as indicators of chronic or lifetime effects. (2) Dosages were changed, stopped and restarted in a vain attempt to extend animal survival, resulting in an inability to relate any cancer effect to any well-defined, constant daily dose. (3) The dose changes reduced the experiment to essentially a single average dose, rather than the multi-dose experiment needed to model risk data. (4) The stomach tube or intubation dosing delivered a highly irritant chemical directly to a sensitive stomach tissue as a single large insult in a short time, resulting in tissue damage which could in itself initiate tumor formation and obscure any direct effect of the chemical. (5) By virtue of EDB's strong irritancy when delivered as a single volume in high concentration, and the natural rejection/elimination of irritants via the gastrointestinal tract, great uncertainty was introduced as to the actual fraction of a delivered dose that might have been retained by any given dosed animal.

Beyond these design and execution flaws, the basic intubation or gavage bioassay of 1978 simply doesn't constitute a model for trace feeding exposure in either animals or humans. In recognition of this point, when the U.S. Environmental Protection Agency attempted in PD 2/3 to model the data from this flawed experiment for risk assessment purposes, they devised a scheme for translation of the intubation results for EDB into theoretical feeding results by using a potency ratio for the two exposure modes derived for an entirely different chemical, dibromochloropropane. This empirical procedure has no scientific justification.

Finally, therefore, there remains to be evaluated the premise as to whether the data from such a flawed bioassay can even be used in the regulatory steps of a so called risk assessment, involving: (1) the fitting of animal data to some form of equation that is linear at low dosage; (2) adding a species-to-species translation factor to convert this animal-fitted equation into one for prediction of human cancer rates; and (3) then using the transformed equation, with all its assumptions, to try to estimate lifetime cancer risks for humans exposed repeatedly to extremely tiny concentrations (at the parts per billion level) of EDB in foods or water. We hold that this process is simply indefensible on any basis, and that the risk probabilities estimated in PD 2/3 and PD 4 based on this bioassay are meaningless. The results of a heavily flawed experiment cannot be improved by any manipulations or transformations, mathematical or otherwise.

We would also question seriously whether the setting of an action level for EDB residues in foods or water at some trace level such as 1 ppb has any scientific justification based on the cancer results of the 1978 rat bioassay and the negative cancer epidemiology in worker populations. Such a level appears to be essentially a zero tolerance, set at the current level of detection of EDB, and not based on avoidance of some specified level of cancer risk.

## STATEMENT OF HONORABLE DOYLE CONNER, COMMISSIONER OF AGRICULTURE, FLORIDA

I am Doyle Conner, Commissioner of Agriculture for the State of Florida. I appear today to respond to your invitation to relate our experiences in Florida to the ethylene dibromide problem.

You have asked for information on the exposure level of the people of Florida and the United States to this chemical. Exposure will differ for each individual based on intake of products which are contaminated with residues of the chemical. I must defer this question to professional scientists.

You have asked, how dangerous is this exposure? Again, I must defer to health professionals.

In response to your third question, what steps should be taken to lower the exposure to EDB, I can relate what we have done in Florida with regard to this problem. On September 16, I prohibited the further use of ethylene dibromide as a soil fumigant. On September 30, 1983, the Environmental Protection Agency announced a ban on the sale and distribution of ethylene dibromide as a soil fumigant and proposed cancellation of its use as a post-harvest fumigant by September 1, 1984.

In view of the fact that some large stocks were in hands of users and could have been applied under the EPA order, I imposed an emergency order halting the use of EDB as a soil fumigant on October 7. I felt this was necessary because of our concern for the health of our citizens, and concern for our environment.

The primary responsibility of our department is regulation of our food supply. This responsibility and the knowledge that ethylene dibromide had been used for years to fumigate stored grain products led us to investigate a number of food products.

We have a very competent staff in our Chemical Residue Laboratory. In September, 1983, these chemists began testing food items which we suspected might contain EDB residues. Our sampling was done in grocery stores and warehouses to locate products most likely to have been exposed to this chemical in storage or processing.

On or about December 5, 1983, I wrote to the federal Food and Drug Administration asking for a regulatory strategy with regard to EDB. The FDA replied there were no federal regulatory standards.

Our laboratory staff tested a number of samples of baby food, cereals, meat, milk, eggs, peanuts, flour and milled corn products. They began finding residues of 1 part per billion or more in a number of the milled corn products in early December.

In the absence of a national guideline, early in December I asked our State Health Officer (Dr. Stephen King) to recommend a level for EDB residues in food as a state guideline. He recommended that the detection limit, 1 part per billion, be established as our action level for the removal of food products from the marketing chain.

Our first recall of products was issued on December 9, after our

State Health Officer recommended setting a state action level of 1 part per billion, the detection limit for this chemical.

On December 22, I joined with Governor Bob Graham to again urge the EPA to establish a federal guideline that would apply to all states, since we agreed that it would be inappropriate for each state to set its own course. The EPA replied that it saw no need to act until it had reviewed tests from Florida and the Food and Drug Administration and all the pertinent data, promising to complete the review shortly after the first of the year. We now understand that sometime in February, EPA will issue its findings.

We have issued recalls for 77 separate lots of manufactured products including cake mixes, pancake and waffle mix, cornbread mix, grits, cornmeal, popcorn and some wheat flour.

We have stressed that there does not appear to be an imminent hazard to human health in consuming these products. Without a doubt, many people have been consuming EDB in minute amounts for many years without knowing it. We do feel that so little is known about the long-term, chronic effects of this chemical, it is best to have them off the market than to let people continue to consume them, especially in view of the fact that some people in Florida may have been consuming water containing minute residues of EDB as well.

As a result of Florida's initiative in testing food products, other states either began similar programs or set about planning them. In recent weeks, tests in Texas confirmed residues in 29 lots of products similar to those tested and found contaminated in Florida. A number of other states are testing, but no other state has established an action level for removal of products. They are awaiting federal recommendations.

For my part, I also have stated on numerous occasions when a federal level is established and recommended, Florida will adopt it because we do not want 50 separate state action levels. We have also repeatedly urged the Environmental Protection Agency to come forward with the federal recommendations, and I know it is working toward that end with all possible speed.

Now, a word about the future.

We realize that agriculture in Florida is under attack from many kinds of insect, disease and fungus which could severely limit our production of food. We realize that at this time, the use of pesticides is necessary to protect our crops and livestock. However, we do not want to cause harm to the environment or to human health.

The Florida Legislature included in the Water Quality Assurance Act of 1983 a provision for creation of a new Bureau of Product Data Evaluation to help us determine which pesticides may be used safely in Florida, taking into consideration the toxicological, hydrological and biological aspects of such use. This bureau is now manned and ready to begin work on these important tasks which lie ahead.

It is our hope that with the addition of these experts, Florida will not be permitting the use of products which may endanger or threaten human life or health or which will have the potential for environmental harm. We do not wish to go off on our own, however, and want to work with EPA, FDA and USDA.

In conclusion, I wish to state that we are aware of efforts on a nationwide basis to draw up regulations to set standards for agricultural chemicals--although we take pride in our own state's efforts in this area. We are in favor of promoting sound crop, soil and water management practices to minimize the environmental hazard from pesticides and other agricultural chemicals.

We believe that in many cases it is possible through modeling to predict in advance the potential for agricultural chemical movement to ground water, and we are anxious to see this development applied to the most widely used chemicals.

With regard to chemicals occurring in food, we urge federal establishment of standards as expeditiously as possible for any chemical which has the potential for either imminent hazard or long-term chronic harmful effects. We recognize that the federal Environmental Protection Agency has the expertise to establish these standards, taking into account the costs and benefits in arriving at safe levels for these compounds.

# STATEMENT OF STEPHEN H. KING, M.D., STAFF DIRECTOR, HEALTH PROGRAM OFFICE, DEPARTMENT OF HEALTH AND REHABILITATIVE SERVICES, AND STATE HEALTH OFFICER FOR FLORIDA

CHAIRMAN HAWKINS, MEMBERS OF THE COMMITTEE:

Thank you for the opportunity to speak before you. I will attempt to answer the questions in your letter of 16 January 1984.

## I. "What is the level of EDB the people of Florida and elsewhere in the United States are exposed to?"

To the best of our knowledge, Florida's residents are exposed to EDB from two main sources, drinking water and grain products in food. Individual risk depends on the length of exposure and the degree of contamination from both of these sources. To determine actual exposure for individuals would be an extremely difficult, expensive and perhaps impossible epidemiologic study.

There have been allegations that widespread EDB contamination may be due to its extensive use as a gasoline additive. However, none of the well water contamination found thus far, and presumably none of the grain contamination as well, is attributable to EDB uses other than its pesticide applications.

Thus far, the Department of Health and Rehabilitative Services (HRS) laboratory, with assistance of the Florida Department of Agriculture and Consumer Services (DACS) laboratory, has tested about 3,000 wells — approximately 20 percent of which are positive. I have attached for your information the most recent summary of the results of that testing, which is arrayed by county and type of well.

Other possible sources of chronic exposure to large segments of the Florida population include EDB residues in grain products. These grains become contaminated during storage, transport, or milling where EDB fumigation has been used for pest control. Exact details on the levels of EDB found in retail food products can be provided to you by Commissioner Connor's agency (DACS). The Florida Department of Agriculture Laboratory has primacy in this state for testing food products.It is important to look at their results before and after food preparation.

It is possible that internationally imported tropical fruit may have been fumigated prior to importation and become a source of exposure. Citrus shipped to other states also may be a source of exposure, but only in those three states -- Arizona, California and Texas (as well as Japan) -- that require fumigation prior to shipment from Florida and elsewhere.

At this point, I would like to review for you how Florida became so concerned about EDB. Beginning in July 1983, the State of Florida embarked upon a program which monitored our drinking water for ethylene dibromide (EDB) contamination. This program began as a result of prior discoveries in Hawaii and California. Those areas of the state given first priority were the eight counties where EDB had been used as a soil fumigant for nematode control in citrus by the Florida Department of Agriculture on citrus. As a result of later disclosures of widespread private use of EDB, well testing is now being conducted on a statewide basis.

The State of Florida's overall response to EDB groundwater contamination is coordinated through an inter-agency Task Force appointed by the Governor. The Task Force is comprised of four agencies - the Departments of Agriculture and Consumer Services (DACS), Community Affairs (DCA), Environmental Regulation (DER), and Health & Rehabilitative Services (HRS) — and chaired by Mr. Rhodes of DER. In addition to laboratory testing, our efforts have been directed at individuals served by water supplies contaminated by EDB at or above a level of 0.1 parts per billion (.1 ppb). These families have been advised by me to use alternative sources of water for drinking and cooking.

The Task Force has provided alternate water to these families through efforts financed and organized by the Department of Environmental Regulation. At the local level, staff of the Department of Community Affairs, with assistance from local county health units assures the actual delivery of water. In addition, DER has conducted tests to determine methods of filtering contaminated wells. DER also is now financing an accelerated well testing program through cooperation with HRS and university laboratories, and local county health units. Hopefully, this accelerated testing program will define the complete scope of our groundwater problem within the next three months.

## II. "HOW DANGEROUS IS THIS LEVEL OF EXPOSURE?

As State Health Officer, I have relied on Ethylene Dibromide (EDB) Position Document 4, Office of Pesticide Programs, U.S. Environmental Protection Agency, September 27, 1983, for reference in determing the degree of danger presented by this chemical. All the information available in this document, which is the final position of the EPA, states that this chemical is highly carcinogenic and mutagenic, and produces adverse reproductive effects. According to this document, there is no apparent threshold effect for this chemical, that is, there is no measurable level below which the adverse effects of EDB are not seen.

Most public health advisory activities are initiated when analysis shows the presence of a chemical in our environment will cause at least one excess malignancy in 100,000 persons exposed to the chemical for a lifetime. Position Document 4 states that consumption of EDB-contaminated grain products at 30 ppb, and water contaminated at 1 ppb, would cause an additional 480 malignancies per 100,000 persons. If this degree of effect is accurate, it is clearly excessive.

## III. "WHAT STEPS SHOULD BE TAKEN TO LOWER EXPOSURE TO EDB?

While our water testing program in Florida is not yet complete, the bans on soil fumigation imposed by the Florida Department of Agriculture and the EPA should prevent further groundwater contamination in this state and nationally. However, simply assessing the presence of contamination resultant from past applications, (some as long as 15-20 years ago) continues to be a lengthy process for Florida, much less the rest of the nation. We plan to test an additional 5-10,000 wells in the next three months, with no assurances that even this number defines the outer limits of the problem. Cleanup will be even more costly — an estimated $5 million in Florida alone for filtration devices and other costs.

The grain problem is national in scope. The exemption from registration of EDB for grain, mill and soil fumigation granted in the 1950's was based on the assumption that EDB would quickly degrade and evaporate, leaving no persisting soil or grain residues. This has not proven to be true, although the exemption remains in existence. I urge that this exemption be addressed immediately.

When the Florida Department of Agriculture found EDB contamination in grain products in early December 1983, I was faced with outdated and inappropriate federal standards, and with overwhelming evidence assembled by the EPA on the degree of danger inherent in this chemical. As a result, as the State's Health Officer, I felt I had no choice but to recommend that products contaminated with EDB at 1 ppb -- the current limit of reliable detection -- or more not be consumed by the citizens of the state of Florida.

Grain and water are among our nation's -- and indeed the world's -- most valuable resources. EPA Position Paper 4 definitively states the potential danger to these resources from EDB. Elimination of this threat is clearly a national issue requiring careful analysis. Acceptable residues (if any) in food products must be prudently set by the EPA, and as quickly as possible. In the absence of such standard-setting, however, we can do no less as state officials than exert our best efforts to protect the health of our citizens.

I would like to close by asking that those who are in a position to shape and implement public policy recognize that one of their first responsibilities is to protect the public's health. St. Thomas Aquinas, I believe, said something to the effect that real generosity toward the future consists of giving all to what is present. It is in that spirit that I urge the EPA to set standards for human exposure to EDB immediately. Madame Chairman, I hope you will join me in this request.

STATE OF FLORIDA
Department of Health and Rehabilitative Services

EDB Surveillance 1983-84
Time Period 7/16/83 to 1/18/84

| District/ County | Municipal Wells | | | Community & Public Wells | | | Private Wells | | | Grand Total | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Wells Tested | Trace EDB | 0.1ppb EDB | Wells Tested | Trace EDB | 0.1ppb EDB | Wells Tested | Trace EDB | 0.1ppb EDB | Total Tested | Trace EDB | 0.1ppb EDB |
| I | | | | | | | | | | | | |
| Escambia | 0 | | | 3 | | | 0 | | | 3 | 0 | 0 |
| II | | | | | | | | | | | | |
| Bay | 1 | | | 4 | | | 1 | | | 6 | 0 | 0 |
| Calhoun | 2 | | | 0 | | | 10 | | | 12 | 0 | 0 |
| Gadsden | 0 | | | 0 | | | 4 | | | 4 | 0 | 0 |
| Jackson | 25 | | 8(32.0) | 20 | 2(10.0) | 1(5.0) | 178 | 18(10.1) | 29(16.3) | 223 | 20(9.0) | 35(15.7) |
| Hernando | 1 | | | 5 | | | 0 | | | 6 | 0 | 0 |
| Wakulla | | | | | | | 1 | | | 1 | 0 | 0 |
| III | | | | | | | | | | | | |
| Citrus | 0 | | | 1 | | | 0 | | | 1 | 0 | 0 |
| Columbia | 0 | | | 8 | | 1(12.5) | 1 | | | 9 | 0 | 1(11.1) |
| Lake | 13 | | | 18 | | 5(27.8) | 185 | 12(6.5) | 49(26.1) | 216 | 12(5.6) | 54(25.0) |
| Marion | 14 | | 3(37.5) | 22 | 1(4.5) | 2(9.1) | 41 | 2(4.9) | 2(4.9) | 77 | 3(3 9) | 7(9.1) |
| Putnam | 3 | | | 2 | | | 2 | | | 7 | 0 | 0 |
| IV | | | | | | | | | | | | |
| St. Johns | 1 | | | 7 | | | 8 | | | 16 | 0 | 0 |
| Volusia | 8 | | | 23 | 1(4.3) | 1(4.3) | 48 | | 2(4.2) | 79 | 1(1.3) | 3(3.8) |
| V | | | | | | | | | | | | |
| Pasco | 2 | | | 1 | | | 1 | | | 4 | 0 | 0 |
| Pinellas | 9 | | | 1 | | | 3 | 1(33.3) | | 13 | 1(7.7) | 0 |
| VI | | | | | | | | | | | | |
| Hardee | 1 | | | 2 | | | 3 | | | 6 | 0 | 0 |
| Highlands | 17 | 1(5 9) | 2(11.8) | 73 | | 13(17.8) | 331 | 6(1.8) | 53(16.0) | 421 | 7(1.7) | 78(18.5) |
| Hillsborough | 16 | 2(12.5) | | 5 | | | 111 | 3(2.7) | 36(32.4) | 132 | 5(3.8) | 36(27.3) |
| Manatee | 3 | | | 0 | | | 18 | | 4(22 2) | 21 | 0 | 4(19.0) |
| Polk | 77 | | 7(9.1) | 90 | 3(3.3) | 10(11.1) | 874 | 25(2.9) | 129(14.8) | 1041 | 28(2.7) | 146(14 0) |
| VII | | | | | | | | | | | | |
| Orange | 19 | 2(10.5) | 6(31.6) | 23 | 1(4.3) | 9(39.1) | 275 | 2(0.7) | 34(12.4) | 318 | 5(1.6) | 49(15.4) |
| Osceola | 5 | | | 2 | | | 11 | | | 18 | 0 | 0 |
| Seminole | 27 | 4(18.2) | 10(45.5) | 13 | | 2(15.4) | 92 | 6(6.5) | 7(7.6) | 132 | 10(7.6) | 19(14.4) |
| VIII | | | | | | | | | | | | |
| Collier | 24 | | | 0 | | | 0 | | | 24 | 0 | 0 |
| Lee | 1 | | | 0 | | | 0 | | | 1 | 0 | 0 |
| Sarasota | 2 | | | 0 | | | 0 | | | 2 | 0 | 0 |
| IX | | | | | | | | | | | | |
| Martin | 0 | | | 2 | | | 4 | | | 6 | 0 | 0 |
| St. Lucie | 0 | | | 6 | | | 4 | | | 10 | 0 | 0 |
| X | | | | | | | | | | | | |
| Broward | 9 | | | 1 | | | 0 | | | 10 | 0 | 0 |
| XI | | | | | | | | | | | | |
| Dade | 37 | | | 19 | | | 5 | | | 61 | 0 | 0 |
| Bottled | 0 | | | 50* | | | 0 | | | 50* | 0 | 0 |
| Totals | 317 | 9(2.8) | 36(11.4) | 401* | 8(2 3) | 44(12.5) | 2211 | 75(3.4) | 345(15.6) | 2930* | 92(3.2) | 432(15.0) |

*Excluded from calculations for total percentages.

## STATEMENT OF DR. JAMES IMRE SZABO

## WINTER GARDEN, FLORIDA

EDB, ethylene dibromide has always been with us. Its concentration varies with light, temperature, humidity, and the concentration of Bromine in the area and of catalysts and of the organic substrates present; as well as with the wind currents, lightning and so forth. That would both create and destroy it. For example, it is formed during the arctic winter reaching its highest levels in the arctic spring.

Decomposition is accelerated with heat, light, movement of air, and water currents and by the presence of catalysts.

The effect of EDB in our food supply depends on many variables: Concentration in dry mass, wet mass, time of exposure, duration and method of exposure, health, nutritional status and digestive, and absorbtion assimilation and elimination abilities of the exposure.

The routes of elimination are feces, urine, saliva, tears, perspiration, and desquamation of skin.

Fifty percent of the intake is eliminated the first 24 hours, half of the remainder the second 24 hours with a fraction of the intake remaining in the body fluids and lipids proportional to its soluability in the substrates.

Before the toxicity mutagenicity and oncologenicity of EDB can be fully understood, its effects must be carefully assessed by controlled studies. If promptly started, good preliminary data should be available in 60 days or a year. Within 4 years most needed accurate information for the further use or disuse of EDB will be present, providing the following is carried out.

Initially, the effects on micro-organisms must be studied. As the effects of varying concentrations of EDB on micro--organisms, mutagenicity, and so forth can only be approximately transferred to human beings, as this knowledge is as yet not entirely specific. I recommend to run simultaneous studies on short-lived species.

I recommend starting the study with fairly large numbers of at least 2 to 3 strains of young female nubile rats with both control and exposed (to various concentrations of EDB for the duration of the experiment) groups being exposed at a steady state for several generations.

The nubile females being on their steady state diet for at least 1 month before being impregnated, then the effects on the litter should be compared to the controls.

Of the second generation of control and exposures some of the rats should be sacrificed and comparisons made with the ovaries, ova, and weights.

The third generation should give the standard and predictable results of exposures to various concentrations of EDB for life times.

The rationale for this study is that the ovare present in females at birth therefore the effects on ova, lifespans and so forth will not be complete until the second and third generations.

Females msut be stressed for reproductive predictions as sperm are being continuously formed and defective sperm will not be as likely to be successful as normal sperm.

The effects of EDB and other toxinogenics are the greatest on the most rapidly growing and multiplying cells, as in the fetus and therefore oncogenicity and mutagenicity will be most noted here with the third generation giving the standard deviations and the development of tolerances and so forth.

The effects of EDB on short-lived species is the greatest. The shorter the lifespan the less the capability of repair. Long-lived species have greater capacity of repair of damaged cell membranes mitochondria, chromosomes, DNA, RNA, and cellular organelles.

The effect of EDB varies with the duration of exposure and the lifespan of the exposed species. For example, a 3-year exposure of a 3-year lifespan species is 100 percent; a 3-year exposure of a 60 year lifespan species is one-twentieth or 5 percent. Therefore, the effect would cause only 5 percent of the cancers and illness found in the 3-year species.

However, frequent and constant insults can and will render the immune system less capable of proper and adequate response, therefore, exposure of humans to EDB may cause an increase of degenerative disease as arthritis, atherosclerosis, lupus, and autoimmune problems as well as rendering them more susceptible to the various infective bacteria viruses that are present in our environment that laboratory animals kept in a controlled environment would or should not be exposed to.

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## STATEMENT OF WILLIAM R. HAVENDER, PH. D.

## BERKELEY, CALIF.

I have been asked to respond to the following questions:

(1) What levels of EDB are people now getting in their food?

(2) What should acceptable levels be?

(3) What, if any, steps can be taken to reduce exposure to consumers?

I will comment on these in turn in the light of Mr. Ruckelshaus' recommendations on Feb. 3, and then will append some pertinent remarks about the risks of EDB's replacements.

Question (1): I do not have independent information on the levels of EDB that consumers are getting in their diet. EPA estimates are in the range of 5 to 10 micrograms per person per day (See the EPA Position Document (PD) 4), and while I suspect this is a generous estimate, I have no solid basis for questioning it and will accept it for the discussion to follow. (By way of comparison, we typically ingest 140,000 micrograms of pepper each day. Ten micrograms is a very small amount, far too small to see with the unaided eye!)

Of more direct importance, of course, is the question of how much carcinogenic hazard this amount actually poses to the public. Several comparisons help put this risk into perspective.

The EPA has estimated that the consumption of wheat contaminated with EDB could lead to as many as 3 extra cases of cancer among 1000 persons exposed for a lifetime (PD 4, Table 11, p. 72). It would be interesting to know how this number, which certainly seems startlingly high, was determined, but not enough discussion of the statistical methodology and assumptions (garbage in, garbage out is as true for statistics as it is for computers) underlying this estimate is given in PD 4 to allow a lay reader to understand how it was derived. (I would urge that an outside statistician, such as Dr. Frank Carlborg of St. Charles, IL, be consulted to review the calculation for consistency with generally accepted risk assessment methodology.)

Let us, however, accept this estimate of EDB's risk to consumers for the moment. One way to put it in perspective is to compare it with the risks of jogging. A paper recently appeared in the Journal of the American Medical Association (Vol. 247., May 14, 1982, p. 2535) on the risks of dying due to jogging in Rhode Island. It estimated the incremental lifetime risk of death from jogging (mostly due to heart attacks) to be 5 per thousand, or nearly twice the estimated risk from consuming EDB.

Another way to put the EDB risk in perspective is to realize that the 3 extra cancer cases per 1000 translates into a *relative* increase in cancer risk of only 1%, since our lifetime cancer risk is already about 300 per 1000 (about 30% of us can expect to get cancer sometime in our lives).

Moreover, we can *test* the EPA's estimate against *real data from human exposure* in the case of EDB, since it has been around a long time, and we have two studies on workers involved in the manufacture of EDB who were exposed to much higher doses than consumers (estimates were 1 to 3 ppm in the air, for periods ranging upwards to sixteen years or more). Such a test of the EPA's estimate is vital, because it derives *entirely* from extrapolations made from animal tests, which extrapolations are crucially dependent upon hypotheses and assumptions (such as that the relation between carcinogenic response and dose is linear over the full range from the animal test doses to the doses typical of human exposure (thousands of times lower), the similarity in sensitivity between animals and humans, the relevance of forestomach tumors (the predominant type seen in the gavage animal studies) to humans (who do not have forestomachs) etc.) A study of this sort was reported in 1978, which applied the statistical model and assumptions the EPA was *then* using to estimate the cancer risk expected among the workers studied. The predicted incidence of cancer, taking the age distribution of the worker population into account, was some ten times higher than that actually observed, which actual rate was not significantly different from that expected in an unexposed population. Moreover, the EPA *changed* the statistical model it uses to a more conservative one (i.e., one that yields even higher estimates of risk) in 1982 (PD 4, pp. 69 - 70), and it is this newer model that was used to generate the estimate of 3 per 1000. Since the old model already yielded risk estimates at least ten times too high, the new model must overstate the risk by even more, but I haven't seen yet a study applying this new model to the worker data, so I will stick with the conclusion that the estimate of 3 per 1000 must be reduced by a factor of at least ten, to .3 per 1000.

But of course this estimate concerns the lifetime risk from a lifetime of exposure. What about the *short term* risk, say, over the next few months? Is this short term risk great enough to justify Florida's declaration of an "emergency" and the issuance of stop-sale orders? This is easy to calculate. Assuming linearity of the dose response and an average lifespan of 70 years, the increase in risk from just the next three months (a period adequate to allow the responsible regulatory and Congressional bodies to hold hearings and convene meetings of scientists to discuss sensible tolerance levels and safe alternatives) would be .3/ (4 x 70) = .00107 per thousand, or about one in one million.

Clearly, no "emergency" existed, and clearly, this level is tolerable while we try to ensure that in banning EDB we don't find outselves having to use something in its stead that will prove to be even more dangerous.

At least two other considerations also argue that the risk from current average levels of EDB contamination in food is negligible. One is that the State of California's OSHA has just recently reduced by a very large amount the allowed levels of EDB in inhaled air that workers may be exposed to, from 20 ppm to 130 ppb. Extensive hearings were held on this matter, and the level of 130 ppb was agreed upon as the level believed to be safe, with an adequate margin of prudence, for workers to breathe in all day, every day, for their entire working life. 130 ppb in air translates into 1 mg/cubic meter, and if we assume that a worker breathes in roughly ten cubic meters of air in eight hours and that all of the EDB is absorbed, then he will be getting a daily body dose of ten milligrams. Well, the EPA's estimates of average daily intake by consumers of EDB from contaminated foods do not exceed ten micrograms, or some thousand-fold lower than the level believed safe for workers. While one can obviously not simply transfer standards appropriate to workers (typically consisting of healthy males in the prime of life) to the diverse population at large (which includes the elderly, the sick, children, pregnant women, etc.), a factor of a thousand is certainly adequate to allow for this diversity. Thus, current average levels of exposure seem quite safe, and the primary regulatory problem is to prevent large excursions above the average level in particular products. (This is just what setting a sensible tolerance level will achieve.)

The other reason for not going into a panic over EDB-contaminated food is that its risk vanishes into insignificance against the background of other, natural carcinogens in food. Pepper contains safrole, for instance, and pepper extracts have caused cancer in mice. Back-of-the-envelope calculations of pepper's carcinogenic "potency", combined with the daily dose humans ingest (about 140 milligrams a day), shows that consumers are exposed to, conservatively, 100 times the carcinogenic risk they would get from EDB residues in food. Aflatoxin, of course, is some thousand times more potent than EDB as a carcinogen (and like EDB, induces a high incidence of lethal tumors in young animals), and the allowed level in food is 15 ppb, which means that consumers are potentially exposed to 1500 times the carcinogenic risk from 10 micrograms of EDB per day. And this doesn't include the risks from the large amounts of highly carcinogenic hydrazines in certain types of mushrooms, the carcinogenic psoralens in celery, the carcinogen, allyl isothiocyanate, in mustard, and many others. Against this natural background of dietary carcinogens, the risk from 10 micrograms of EDB per day is utterly trivial.

Question (2): I have no significant objection to Mr. Ruckelshaus' suggested long term tolerance levels. These provide more than an adequate margin of safety, and yet are achievable by industry. This follows from the fact that the bulk of the food currently on supermarket shelves is already in compliance with these levels; only a very small fraction of the grain-derived food samples in Florida and California exceed them. The few samples falling above 150 ppb are clearly "outliers", no doubt due to accidents, negligence, or other exceptional circumstances rather than to intrinsic difficulties, and they can easily be brought into line with the levels routinely achieved by the rest of the food industry.

I submit, however, that these levels, while excellent for the long term, should not be used to justify pulling products off of shelves in the near term while we are phasing these "outliers" through the system, because the short term risk, even from these outliers, is still insignificant. A muffin baked from the most highly contaminated mix found in California (which had 5.4 parts per million), for example, would have only about one tenth the carcinogenic hazard of a peanut butter sandwich. This follows because aflatoxin in peanut butter at the perfectly legal level of 5.4 ppb would present the same cancer risk as the muffin mix containing 5.4 ppm. But a muffin baked from this mix would have only about one tenth this amount, and since a single muffin weighs roughly about as much as the couple of spoonfuls of peanut butter in a typical peanut butter and jelly sandwich, it is evident that the sandwich poses much the greater risk. If one can eat a peanut butter and jelly sandwich with equanimity, then it makes little sense to worry about EDB residues in food -- even in the most highly contaminated food so far discovered -- during the short time it will take to phase already processed foods through the distribution system.

Indeed, it is morally indefensible to destroy such food when, according to recent reports, hungry people -- concerned far more about starving in the short term than about cancer in the long term -- are still to be found in America.

(Incidentally, there is an interesting synergism between insect and mold contamination. Insects are themselves highly efficient vectors for transporting mold spores and, because they break the physical integrity of seed coats by chewing, facilitate the invasion and implantation of mold spores into grain kernels. Controlling bugs, then, is an important way of keeping mold contamination, with its associated potent cancer-causing toxins, to a minimum.)

Question (3): The main change needed, as alluded to above, is to prevent large deviations from normal levels from occurring. Since practically all grain-based foods are already in compliance with Mr. Ruckelshaus' standards, relatively simple measures, such as aerating grain a bit longer after fumigation, or diluting out grain having unacceptably high residue levels with grain containing acceptable levels, will solve the problem. The primary change needed is not technological but merely administrative; companies need merely to monitor EDB levels, which up until now have been completely unmonitored due to the lack of a tolerance level. The incentive to do such monitoring is exactly what Mr. Ruckelshaus' recommendations will provide.

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However, Mr. Ruckelshaus went beyond the mere setting of tolerance levels. He also ordered the immediate cessation of all use, however monitored and controlled, of EDB in grain and spot fumigation. This is not merely unwarranted, but the most dangerously irresponsible decision involving the public's health that the EPA has taken in its history. Why? Because it forces us to use alternatives that are available right now (I take it as given that no one is seriously recommending, in a hungry world, that we simply let vermin eat up our grain without control), and the plain fact is, there are only a very few that are currently registered for use as grain fumigants. Now any thoughtful person would surely want to know about the hazards, both to consumers and to workers, of these alternatives. In particular, one would like to know what alternatives are available that, in addition to being technically adequate, have been thoroughly tested in the same sort of long term, high dose animal cancer tests that were required to reveal the cancer hazards of EDB and have been given a clean bill of health. The latter is an essential consideration, since if we phase out EDB specifically because of its cancer risk to the public, we certainly don't want to replace it with something that is just as bad in this very same regard, or perhaps worse.

In terms of technically doing the job of EDB in grain fumigation, phosphine and methyl bromide are the preferred alternatives. Both are effective for bulk fumigation, but neither is suited for the spot fumigation of milling machinery. This is because they are far more volatile than EDB (they are gases at room temperature, while EDB is a liquid), and for this reason escape too quickly from the machines before the insects have been killed. So the only way to use these substances to kill bugs inside the machines is to fumigate the whole plant. Rather than just a few gallons of fumigant being needed for the spot treatment of machines as with EDB, many thousands of gallons are necessary to bring the overall concentrations in the plant up high enough to sterilize the machinery. This must be done about once a month, since the generation time of the insects is about four weeks, and it is important to kill the eggs so that they don't germinate on grocery shelves and in kitchen cabinets. As it happens, this change of operation greatly increases the hazards to workers. Methyl bromide is much more toxic to humans than EDB, and moreover is odorless (in contrast to EDB) so that workers do not have a fail-safe warning when they are inadvertently exposed to it. Phosphine, too, is more poisonous to workers than EDB, and in addition is highly flammable. This is a property of substantial concern since grain dust, itself highly explosive, is endemically present in grain bins and mills. (By contrast, both EDB and methyl bromide are flame retardant.) Thus, the substitution of these substances for EDB ineluctably raises the risks to the workers who must use them.

There are those (I am not among them) who might argue that this would be a small price to pay if the risks to the vastly larger number of consumers were substantially reduced, but this is where we meet the final irony. For phosphine has not been tested for carcinogenicity at all, and if we decided today to do so, it would take at least three years before we could have secure assurance that phosphine was not a carcinogen. And as for methyl bromide, it is currently under test, with results expected to be announced in March. (For structural reasons, by the way, it is highly likely that methyl bromide will turn out to be a carcinogen. It is closely related to methyl chloride, a known carcinogen, and it is an alkylating agent like EDB.) Of the two main alternatives to EDB that are currently registered and available, then, we cannot now confidently state that either of them would be any safer than EDB in terms of the cancer risk they pose to the public. Indeed, they could be worse.

A third, less effective alternative sometimes mentioned is a 4:1 mixture of carbon tetrachloride and carbon disulfide. Carbon tet is a carcinogen, and carbon disulfide, if used by itself, is explosive.

Now, it *may* turn out that precisely because methyl bromide and phosphine *are* much more volatile than EDB, it will be possible to get rid of all traces of these residues from consumer products, in which case it would not matter whether they are carcinogens or not. But this is just what was once said about EDB, and it could turn out that these gasses, like EDB, adsorb tightly to the surface of grain in some manner that prevents them from easily passing off. Such tendencies might depend, as is the case with EDB, on the particular type of grain being treated, its moisture content, the ambient temperature of storage, and other factors. In any case, we need to *know* just how much of these residues pass through processing for each type of grain, and end up in diverse consumer products, and in my inquiries, I was not able to discover that this necessary testing had been done.

Moreover, we may well be standing at the beginning of a line of dominos, which will fall under a regulatory ban one by one as more information becomes available. According to PD 4 (Table 26, pp. 196-7), methyl bromide was accepted for "pre-RPAR review" in 1980, and carbon tet was already undergoing RPAR scrutiny, suggesting that these alternatives may well be banned in the near future also. If so, that would leave only the very flammable phosphine, whose carcinogenic hazard is completely unknown.

In short, Mr. Ruckelshaus' recommendations on Feb. 3 have both Solomonic and demonic aspects. The Solomonic aspect is the setting of wise and workable long term tolerance levels. The demonic aspect is his ban on *any* use of EDB for grain and spot fumigation in the future, however carefully controlled and limited. This latter ban *guarantees* greater hazards to workers, even while, perversely, it cannot guarantee that the public's exposure to potent carcinogens will actually be lowered.

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